EXHIBIT A

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(54) **DEVICE FEATURES AND DESIGN ELEMENTS FOR LONG-TERM ADHESION**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 501 days.

This patent is subject to a terminal disclaimer.

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(51) **Int. Cl.**
A61B 5/00 (2006.01)
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(52) **U.S. Cl.**
CPC ***A61B 5/282*** (2021.01); ***A61B 5/25*** (2021.01); ***A61B 5/259*** (2021.01); ***A61B 5/291*** (2021.01);
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(58) **Field of Classification Search**
CPC A61B 5/04; A61B 5/0408; A61B 5/04085; A61B 5/04087; A61B 5/0492;
(Continued)

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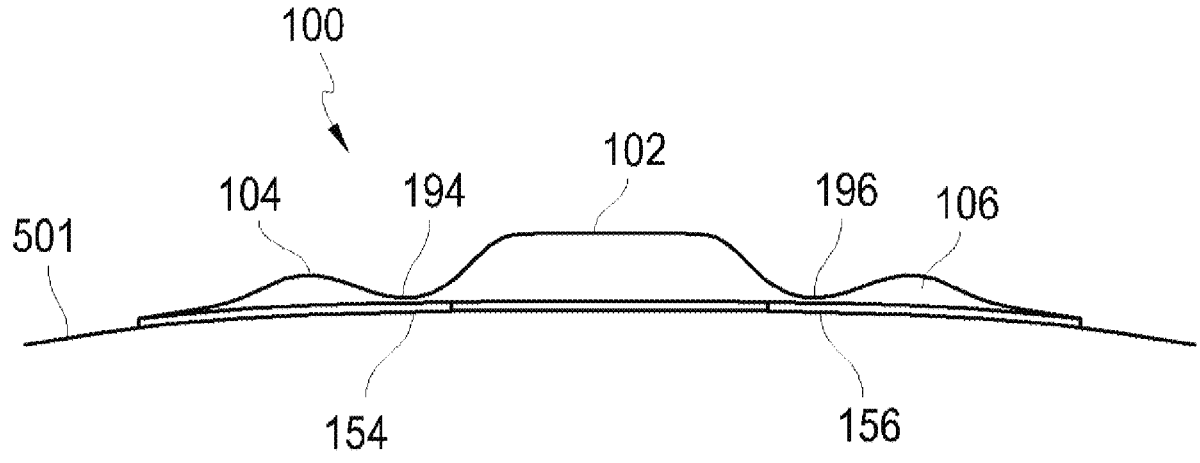
(57) **ABSTRACT**

An electronic device for long-term adhesion to a mammal includes a housing with an electronic component. The electronic device may include a first wing and a second wing, each being integrally formed with the housing. An electrode is positioned on a bottom surface of each of the wings, the electrodes electrically connected to the electronic component. An adhesive layer is provided for adhesion to a surface of the mammal. The adhesive layer may cover a portion of the bottom surfaces of the wings but generally does not cover the electrode or a bottom surface of the housing. A method of applying an electronic device to a mammal includes removing first and second adhesive covers
(Continued)



from first and second wings of the electronic device to expose an electrode and an adhesive coated on a bottom surface of each wing.

12 Claims, 11 Drawing Sheets

Related U.S. Application Data

continuation of application No. 16/138,819, filed on Sep. 21, 2018, now Pat. No. 10,517,500, which is a continuation of application No. 15/005,854, filed on Jan. 25, 2016, now Pat. No. 10,405,799, which is a continuation of application No. 13/890,144, filed on May 8, 2013, now Pat. No. 9,241,649, which is a continuation of application No. 13/563,546, filed on Jul. 31, 2012, now Pat. No. 8,538,503, which is a continuation of application No. 13/106,750, filed on May 12, 2011, now Pat. No. 8,560,046.

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(51) **Int. Cl.**

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(52) **U.S. Cl.**

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(58) **Field of Classification Search**

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See application file for complete search history.

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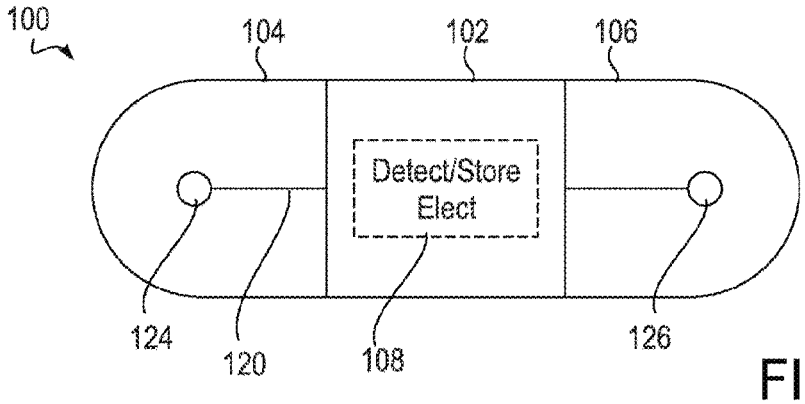
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FIG. 1

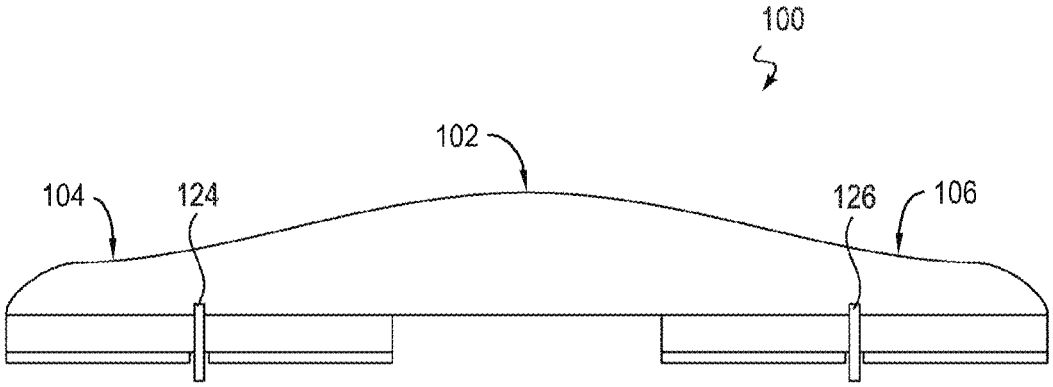
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FIG. 1A

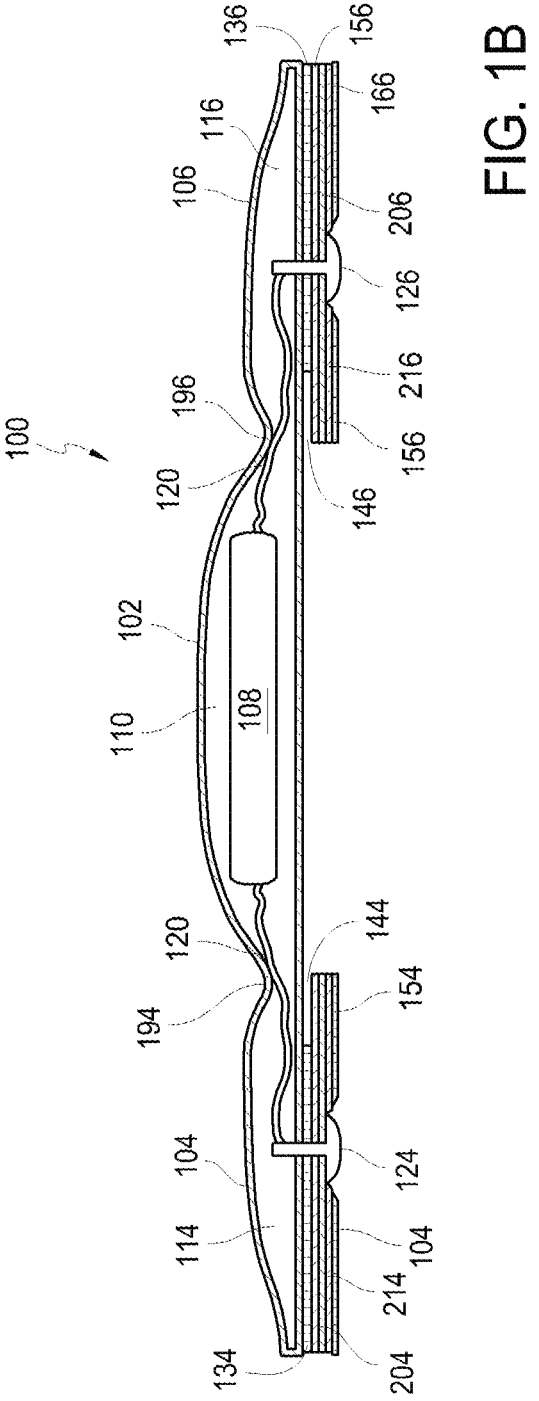
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FIG. 1B

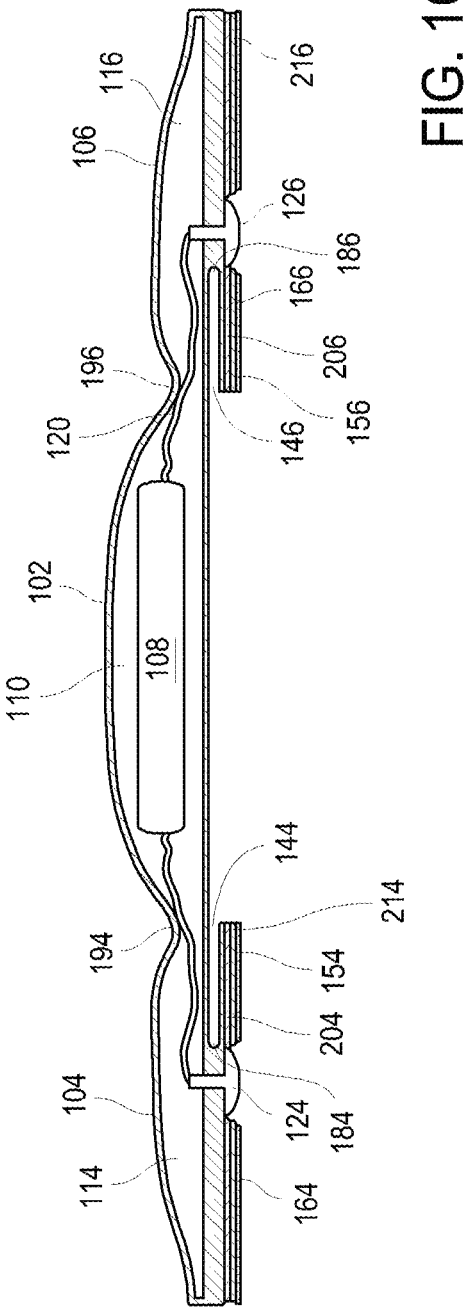
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FIG. 1C

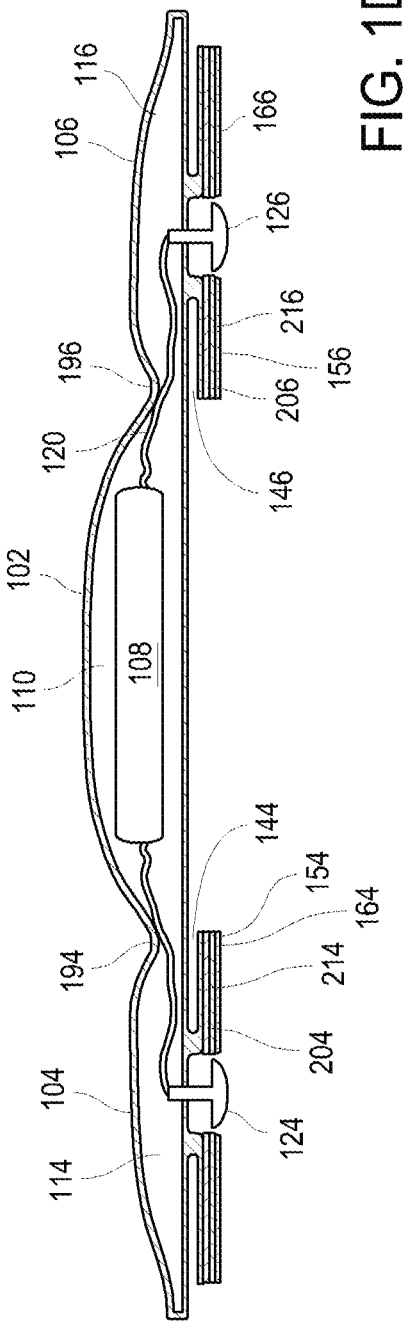
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FIG. 1D

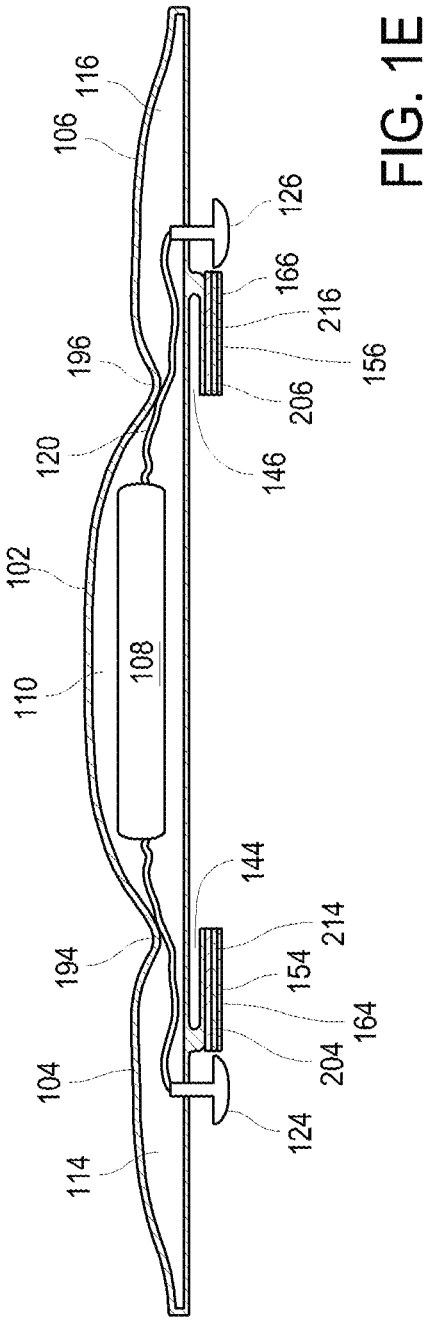
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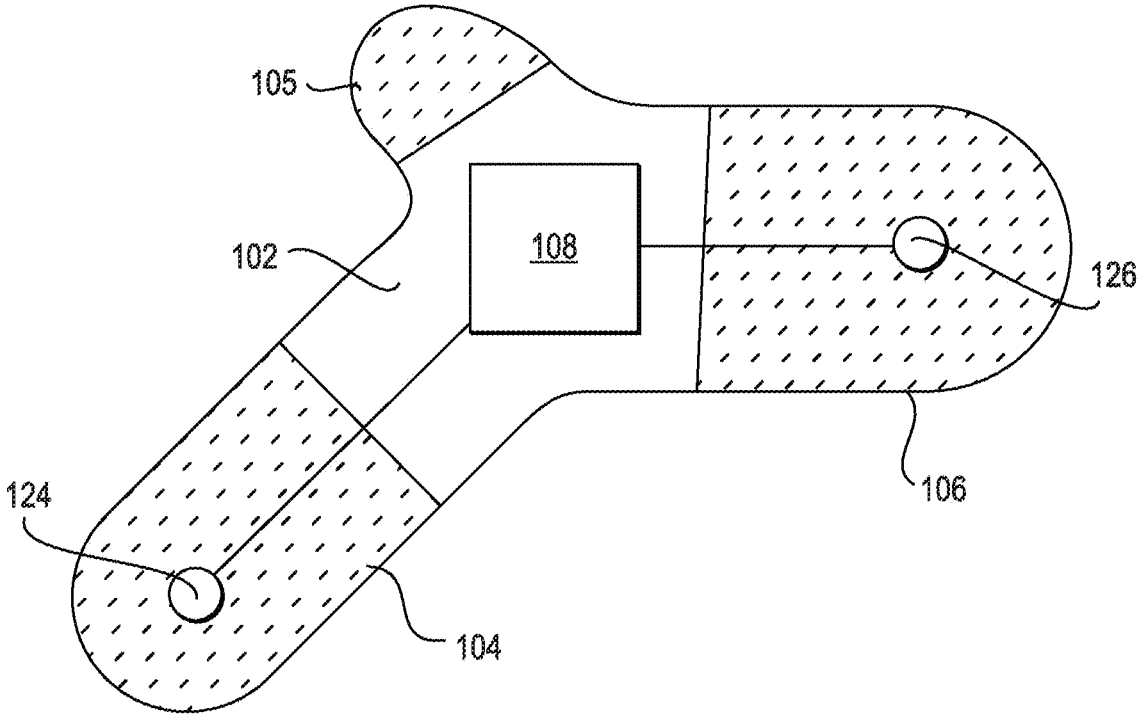
FIG. 1E



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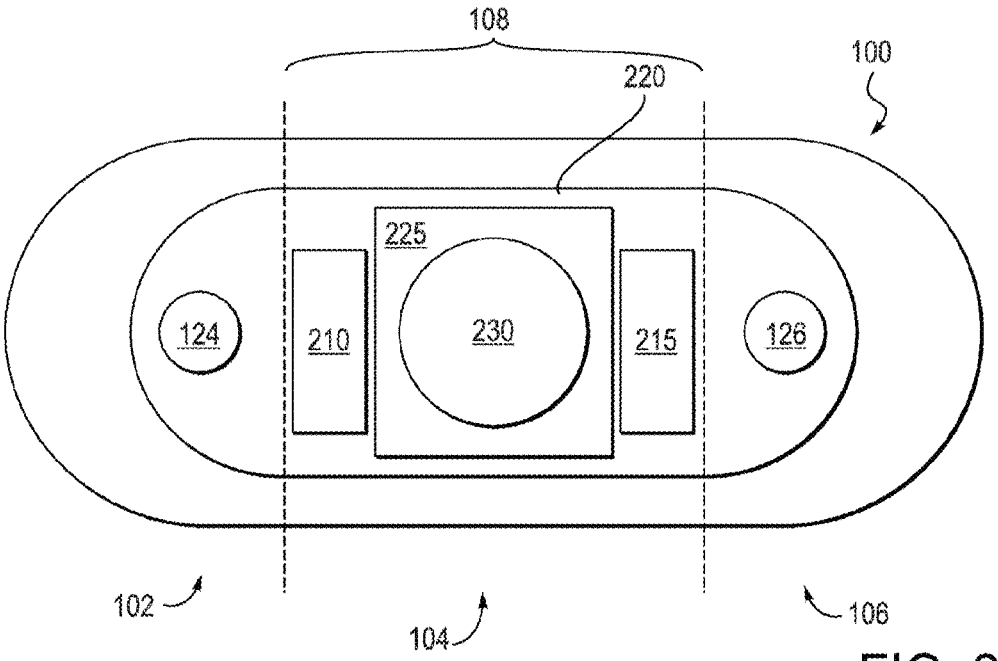


FIG. 2A

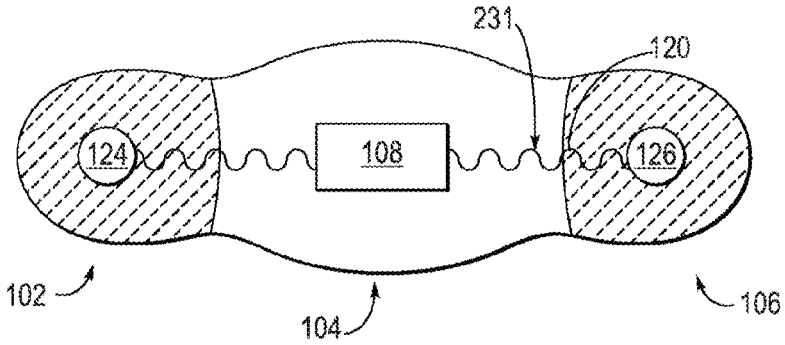


FIG. 2B

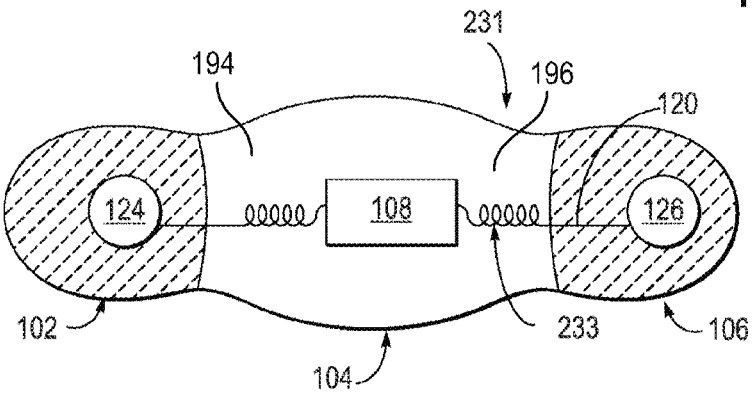


FIG. 2C

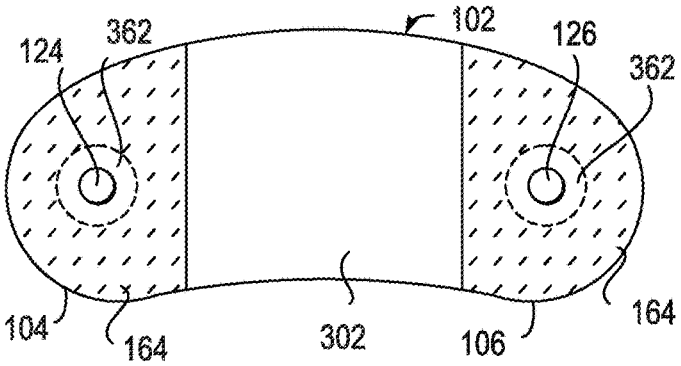


FIG. 3

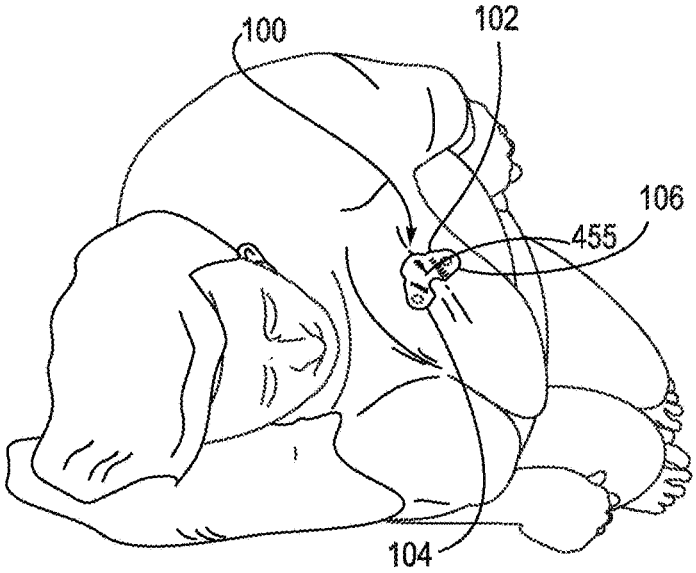
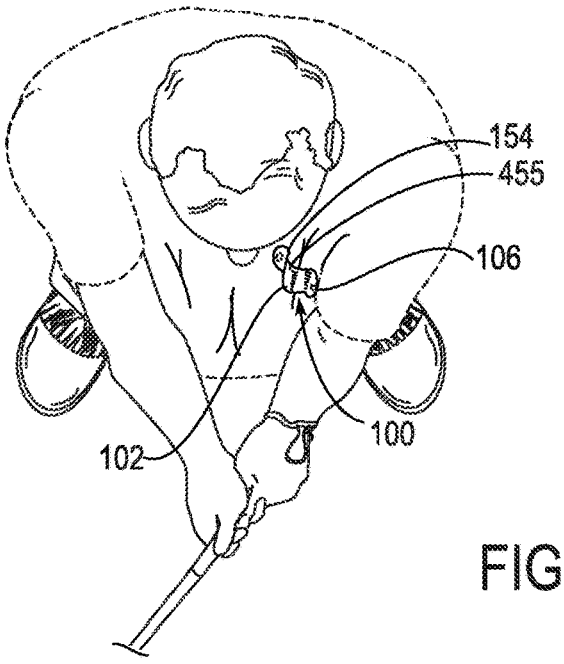


FIG. 4A



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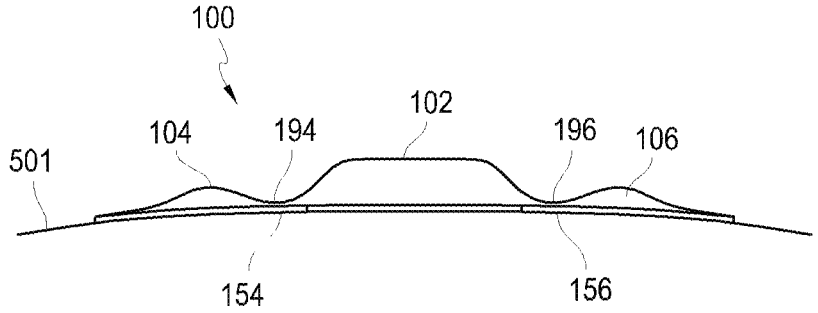
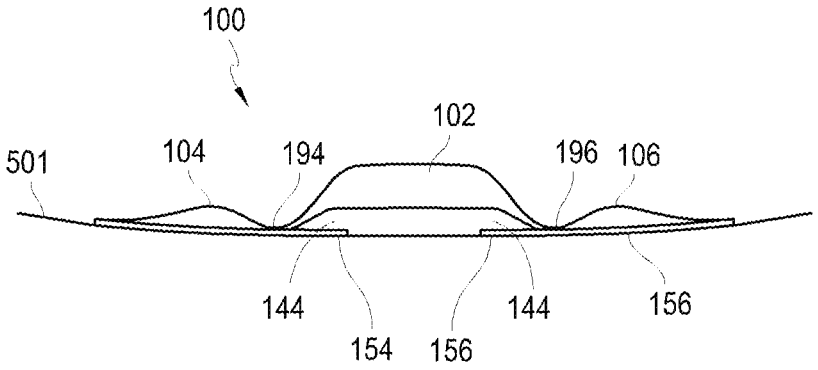


FIG. 5A



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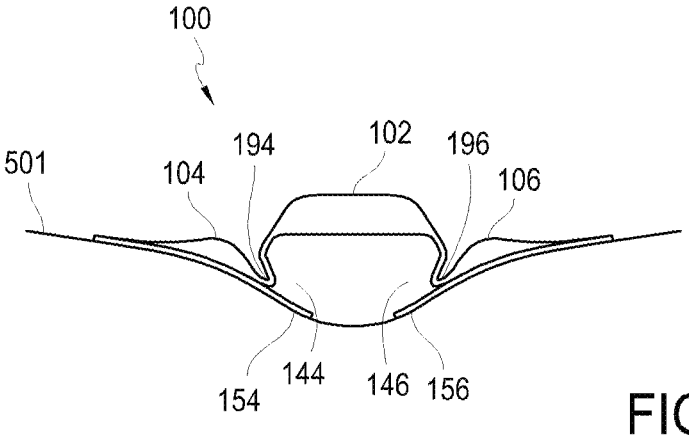


FIG. 5C

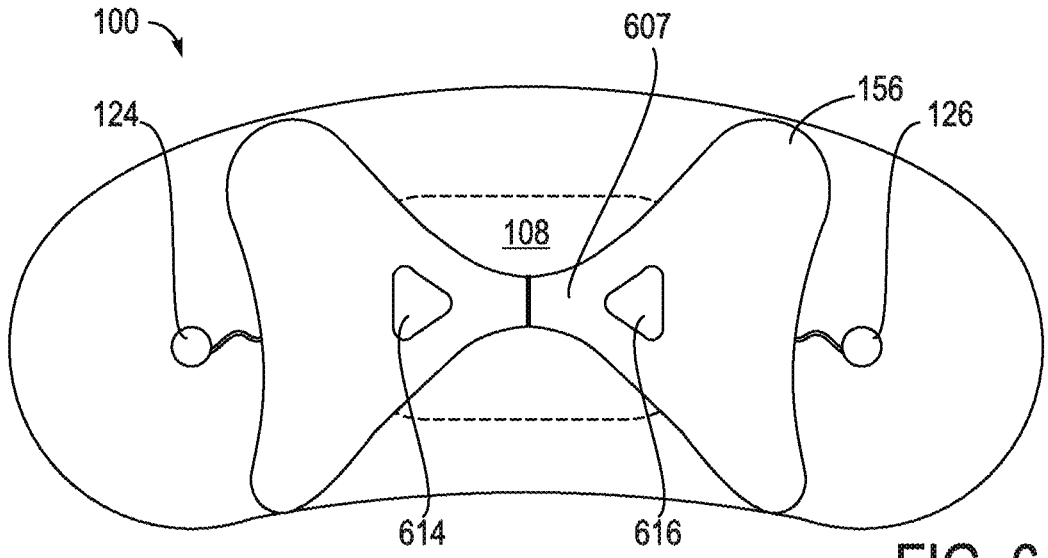


FIG. 6A

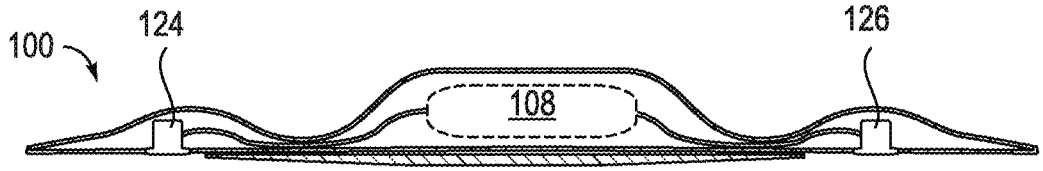


FIG. 6B

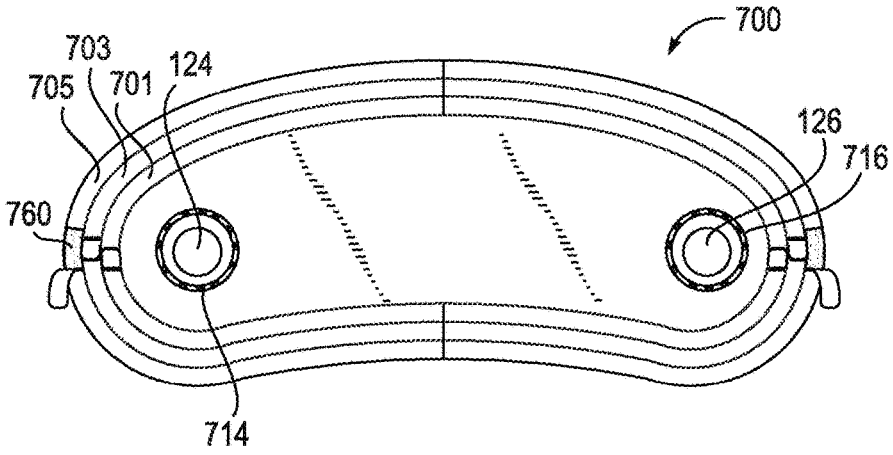
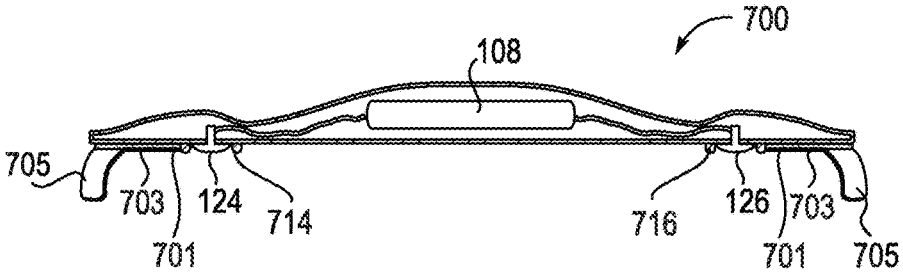


FIG. 7A



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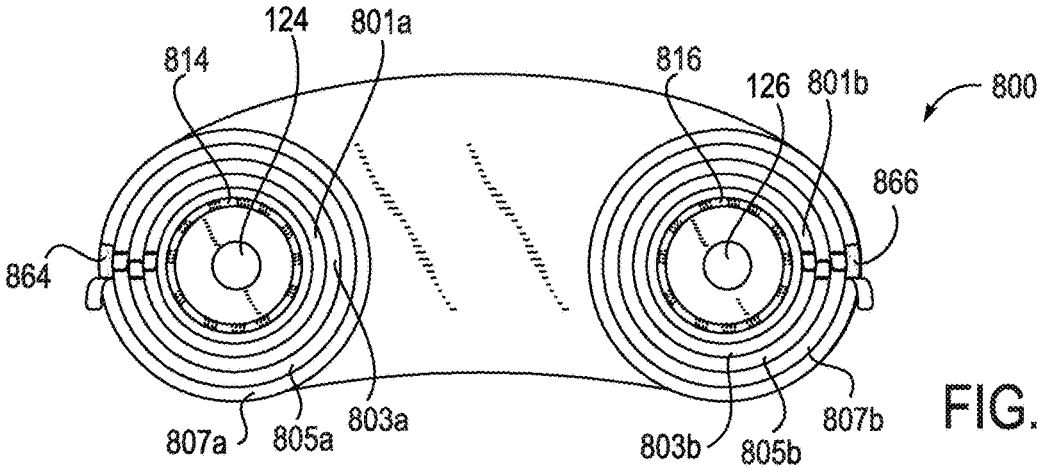
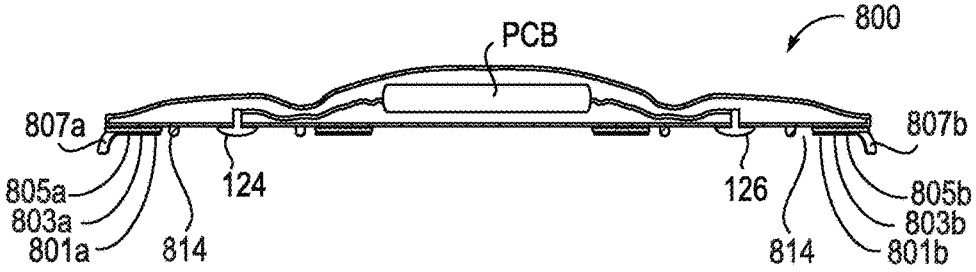


FIG. 8A



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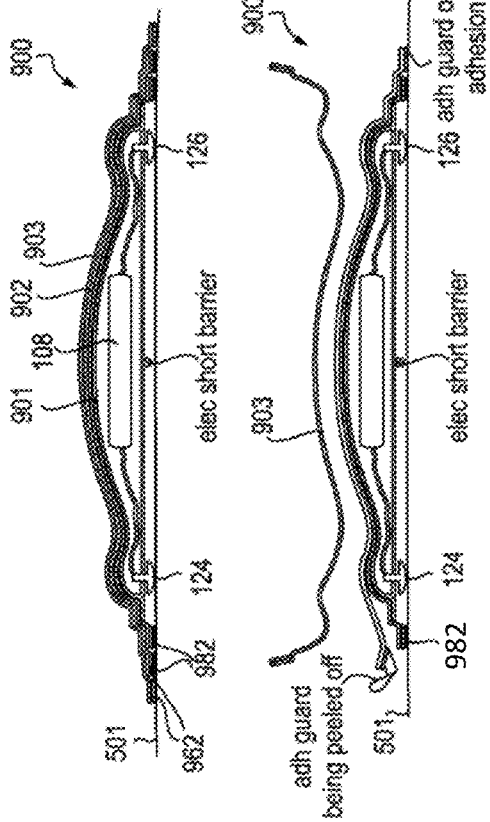

FIG. 9A

FIG. 9B

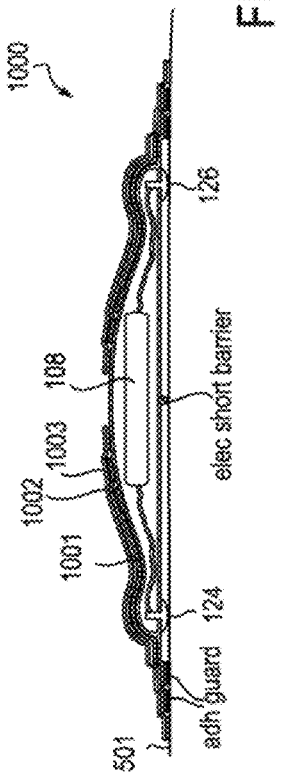

FIG. 10A

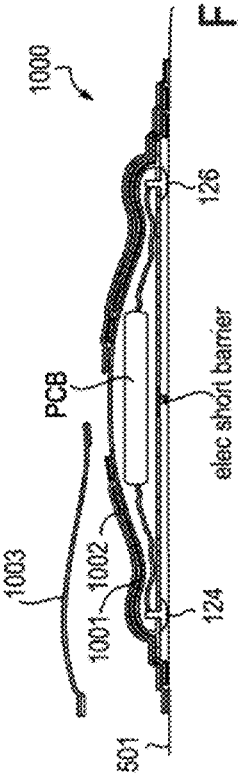

FIG. 10B

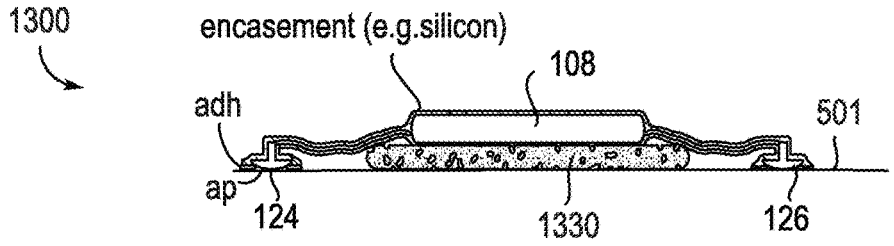

FIG. 11

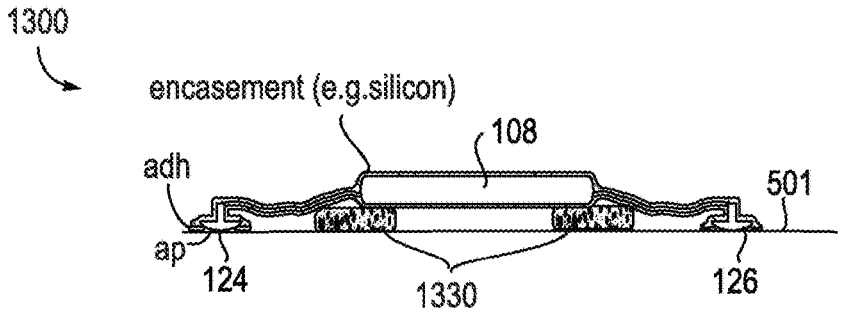

FIG. 12

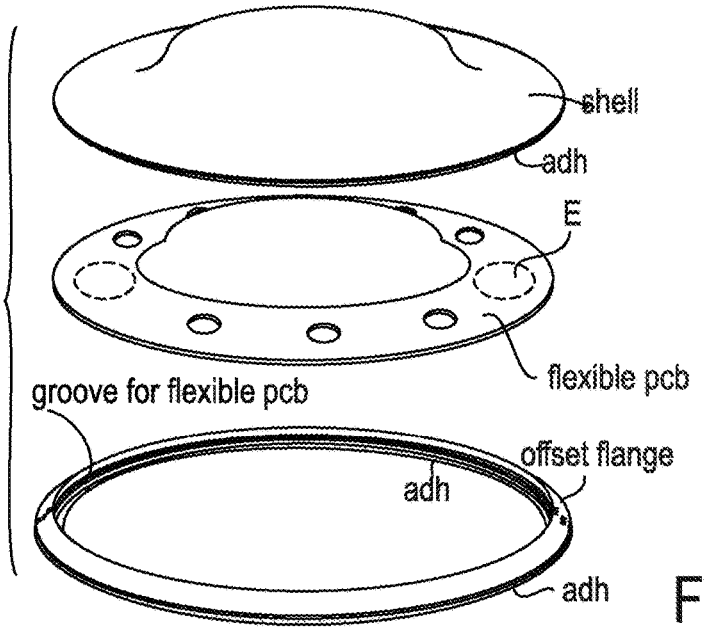

FIG. 13A

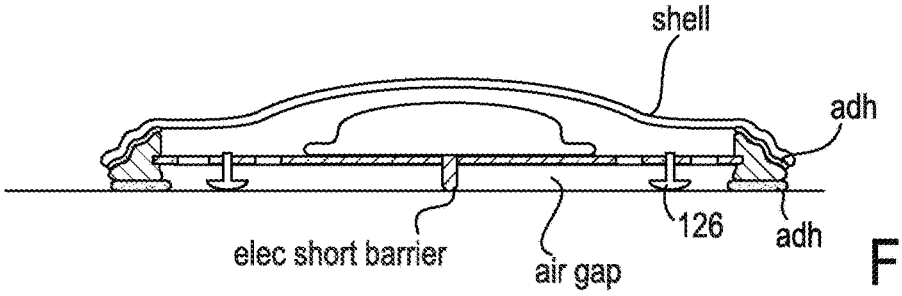

FIG. 13B

DEVICE FEATURES AND DESIGN ELEMENTS FOR LONG-TERM ADHESION

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 16/723,208, filed Dec. 20, 2019, titled "Device Features and Design Elements for Long-Term Adhesion" which claims priority to U.S. application Ser. No. 16/138,819, filed Sep. 21, 2018, titled "Device Features and Design Elements for Long-Term Adhesion" which claims priority to U.S. application Ser. No. 15/005,854, filed Jan. 25, 2016, titled "Device Features and Design Elements for Long-Term Adhesion" which claims priority to U.S. application Ser. No. 13/890,144, filed May 8, 2013, titled "Device Features and Design Elements for Long-Term Adhesion" which claims priority to U.S. application Ser. No. 13/563,546, filed Jul. 31, 2012, titled "Device Features and Design Elements for Long-Term Adhesion", which claims priority to U.S. patent application Ser. No. 13/106,750, filed May 12, 2011, which claims priority to U.S. Provisional Patent Application Ser. No. 61/334,081, filed May 12, 2010, entitled "Device Features and Design Elements for Long-Term Adhesion." All of the aforementioned applications are incorporated by reference as if fully set forth herein.

INCORPORATION BY REFERENCE

All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD OF THE INVENTION

This application relates to devices worn on a body for monitoring, recording, reporting and/or treating the person wearing the device. Improvements in the device design elements and functionality are disclosed for maintaining the device in contact with and operational for extended periods of time, typically longer than 24 hours.

BACKGROUND OF THE INVENTION

The ability to adhere a medical device to a human body for a long-period of time is dependent on a variety of factors. In addition to the type and nature of the adhesive chosen, another factor is the mechanical design of the device. By design, this refers to, but is not limited to, the device shape, size, weight, flexibility, and rigidity. These design elements are influenced by a number of additional factors, including, hut not limited to, where on the body the device will attach and the duration of the attachment, moisture conditions in that area, movement conditions in that area, stretching and contraction in that area, interactions with external factors in that area such as clothing, and purposeful and/or inadvertent interaction between the person wearing the device and the device.

As many are typically used on the body for less than 24 hours, devices have not been designed that can withstand longer-term adhesion. Hence, there is a need to implement device features and design elements that have the ability to enhance the likelihood of adhesion of a device to a human body for 24 hours or more, while accommodating the functionality, shape, size, weight, flexibility, and rigidity of a given device.

SUMMARY

In one aspect of the invention, there is an electronic device for long-term adhesion to a mammal. The device has a housing containing an electronic component with a first wing and a second wing integrally formed with the housing. There is an electrode positioned on a bottom surface of each of the wings with the electrodes electrically connected to the electronic component. An adhesive layer is provided tor adhesion to a surface of the mammal. The adhesive layer is coated on a portion of the bottom surface of the wings. The adhesive layer is not coated on the electrode or on a bottom surface of the housing.

The electronic component in any of the devices described herein may include a processor having a memory with computer readable instructions to record signals from the first and second electrodes while the electronic device is attached to the mammal. The processor may be configured to only convert signals from the electrodes to digital signals, filter those signals and then store the signals in memory.

In another aspect, the device includes a flap connected to each of the wings. The flaps may extend below the housing. Additionally or alternatively, the adhesive layer is coated on a bottom surface of the flaps.

In another aspect, the device includes a connector segment In one aspect, the connector segment configured to connect the flaps together. In other aspects, the connector segment is located at least partially below the housing. Still further, the connector segment is not attached to the housing.

In one alternative, the adhesive layer is coated on a bottom surface of the flap.

In still another aspect, the adhesive for adhesion to a surface of the mammal is an adhesive that can absorb fluids. In another aspect, the adhesive that can absorb fluids is a hydrocolloid adhesive. In another aspect, the adhesive for adhesion to a surface of the mammal is a pressure-sensitive adhesive. The pressure sensitive adhesive is selected from the group consisting of: a polyacrylate, a polyisobutylene, and a polysiloxane. In one alternative, the device includes a diffusion barrier between the adhesive layer and each of the wings. The device may also include an additional adhesive layer and material layer between the wing and the adhesive layer for adhesion to the mammal. The material layer is configured to prevent diffusion of adhesive components from the adhesive layer to the wing. The diffusion barrier may be made from polyester or other suitable synthetic material.

In one aspect of the device, all or substantially all of the electronic components are within the housing. In another aspect, the wing is free from electronic components. In one aspect, the wing is more flexible than the housing. In one alternative, the wings and the housing are made from the same material. In another aspect, the wings and the housing are made from different materials. In another, the wings are made from a fabric. In still another aspect, the material used to make the wings includes a synthetic fiber. In another alternative, the wing and the flap are composed of the same material.

In another alternative, the device includes a hinge portion between the housing wmg, The hinge portion is configured to allow the device to bend between the housing and the wmg. In one aspect, the hinge portion exists between a rigid portion of the device and a flexible portion of the device. In

one alternative, the rigid portion of the device corresponds to the portion of the housing including the electronics and the flexible portion of the device includes a wmg

In one aspect, the bottom surface of the wing and the bottom surface of the flap are contiguous, In another aspect, the bottom surfaces of the wings, the flap, and the connectors are contiguous. In still other aspects, the flaps and the connector are contiguous.

In another aspect, the connector has at least one hole extending it. The hole may have any of a number of shapes such as circular, oval, round, or triangular.

In one aspect, the housing is thicker at a center of the housing than at edges of the housing.

In another aspect of the device, the housing is unattached to the mammal when the electrodes are in contact with the mammal.

In another alternative aspect of a device for long-term adhesion to a mammal, the device includes a housing with a first wing extending laterally from the housing and a second wing extending laterally from the housing without overlapping the first wing, There is a first electrode positioned on a bottom surface of the first wing and a second electrode positioned on a bottom surface of the second wing. An electronic memory is positioned within the housing. The electronic memory is configured to receive and store electronic signals from the first and second electrodes while the electronic device is attached to the mammal. There is also an adhesive layer on a portion of a bottom surface of the first wing and the second wing. The adhesive is not on a bottom surface of the housing. When the device is worn on the mammal, only the adhesive layer(s) are attached to the mammal.

In one aspect, the portion of the bottom surface of the first wing and the second wing does not include the first and second electrodes, In one device aspect, the first wing, the second wing, and the housing are formed from the same material. In still another, the first wing, the second wing and the housing integrally form a monolithic structure. In other aspects, an angle formed by the first wing, the second wing, and the housing is between approximately 90° and 180°, In one variation, the angle is approximately 180°, In another variation, the angle is approximately 135°.

In still other embodiments, there is a first hinged portion between the first electrode and the processor and a second hinged portion between the second electrode and the housing.

In a further aspect, at least a portion of the body uncovered is not adhered to the mammal when signals from the electrodes are being recorded in memory.

In another aspect, the device includes a first flap connected to the first wing medial to the first electrode and a second flap connected to the second wing medial to the second electrode. Each nap may extend below the housing.

The device may also include a connector segment configured to connect the flaps together. In one aspect, the connector segment is located at least partially below the housing, but is not attached to the housing.

In another aspect, there is an electronic device that has a patch including a housing containing an electronic component. There is an electrode positioned on a bottom surface of the patch, the electrode electrically connected to the electronic component. There is a first adhesive strip extending around the perimeter of the patch and a second adhesive strip extending around the perimeter of the first adhesive strip, In one aspect, the first adhesive cover over the first adhesive strip and a second adhesive cover over the second adhesive strip, The first and second adhesive covers may be configured to be separably removed from the first and second adhesive strips, In one alternative, the first adhesive strip extends between the first and second adhesive covers. In another alternative, the adhesive in the first and the second adhesive strips is an adhesive that can absorb fluids. In still another aspect, the adhesive that can absorb fluids is a hydrocolloid adhesive. In one alternative, the adhesive in the first and the second adhesive is a pressure-sensitive adhesive. In some aspects, the pressure-sensitive adhesive is a polyacrylate, a polyisobutylene, or a polysiloxane.

In one alternative, the second adhesive strip partially overlaps the first adhesive strip. In another aspect, the second adhesive strip is attached to a shell, the shell overlapping the first adhesive strip.

In still another alternative device for long-term adhesion to a mammal, the device includes a patch having a housing with an electronic component contained therein, There is an electrode positioned on a bottom surface of the patch, The electrode electrically connected to the electronic component There is a porous foam pad configured to he positioned between the electronic component and the mammal. In one aspect, the porous foam pad comprises a biocompatible foam material. In one variation, the porous foam pad can absorb fluids. In still another aspect, the porous foam pad is attached to the housing. In another, the porous foam pad is configured to be attached to the mammal. In another request, the porous foam pad can absorb fluids.

In one aspect of a method of applying an electronic device, there is a step of removing a first adhesive cover from the first wing of the electronic device to expose an electrode and an adhesive coated on a bottom surface of a first wing, There is a step of placing the exposed electrode into contact with the mammal by adhering the adhesive coated bottom of the first wing to the mammal. There is also a step of removing a second adhesive cover from the second wing of the electronic device to expose an adhesive coated on a bottom surface of the second wing and another exposed electrode, There is also a step of placing the another exposed electrode into contact with the mammal by adhering the adhesive coated bottom of the second wing to the mammal. After performing the removing and the placing steps, the housing is unattached to the mammal, but is held in position on the mammal using the adhesive coated bottoms of the first and the second wings.

In one alternative method of attaching a device, the electronic device includes a first nap connected to the first wing and a second flap connected to the second wing. The first and second flaps each extend below the housing. The step of removing a first adhesive cover from the first wing may also include exposing an adhesive coated on a bottom surface of the first flap. The step of removing a second adhesive cover from the second wing may also include exposing an adhesive coated on a bottom surface of the second flap.

In another alternative method of attaching a device, after performing the removing and the placing steps, the housing is held in position on the mammal using only the adhesive coated bottoms of the first wing, the second wing, the first flap and the second flap.

In an alternative aspect of a method of applying an electronic device to a mammal for long-term adhesion, the method includes removing a first adhesive cover from the first wing of the electronic device to expose an electrode and an adhesive coated on a bottom surface of the first wing. There is also a step of removing a second adhesive cover from the second wing of the electronic device to expose an adhesive coated on a bottom surface of the second wing and

another exposed electrode. There is a step of placing the exposed electrodes into contact with the mammal by adhering the adhesive coated on the bottom of the first and the second wings to the mammal, After performing the removing and the placing steps, the housing is unattached to the mammal, but is held in position on the mammal using the adhesive coated bottoms of the first and the second wings.

There is also provided a method of applying an electronic device to a mammal for long-term adhesion wherein the electronic device includes a patch. The patch includes an electronic component along with an electrode positioned on a bottom surface of the patch and electrically connected to the electronic component. There is a first adhesive strip extending around the perimeter of the patch and a second adhesive extending around the perimeter of the first adhesive strip. One aspect of a method of applying the device includes a step of removing an adhesive cover from the second adhesive strip of the electronic device. There is a step of applying pressure to the second adhesive strip to adhere the second adhesive strip to the mammal such that the electrode is in contact with the mammal. Then, after a period of time, removing an adhesive cover from the first adhesive strip of the electronic device. Next, there is the step of applying pressure to the first adhesive strip to adhere the first adhesive strip to the mammal such that the electrode remains in contact with the mammal.

In another alternative method of applying an electronic device to a mammal for long-term adhesion, the electronic device includes a patch, an electronic component, and an electrode positioned on a bottom surface of the patch and electrically connected to the electronic component. There is a first adhesive strip extending around the perimeter of the patch. The method includes a step of applying pressure to a first adhesive strip to adhere the first adhesive strip to the mammal such that the electrode is in contact with the mammal. After a period of time, placing a second adhesive strip around the perimeter of the first adhesive strip. Then there is the step of applying pressure to the second adhesive strip to adhere the second adhesive strip to the mammal such that the electrode remains in contact with the mammal.

Any of the above described devices may include additional aspects. A device may also include a first wire connecting the first electrode and the processor or an electronic memory and a second wire connecting the second electrode and the processor or an electronic memory. The first and second wires extend within the body and the first and second wings. In one aspect, the first and second wires extend within and are completely encapsulated within the body and the first and second wings. In one aspect, a conduit is provided within the body and the wings and the wires pass through the conduit. In one alternative, the conduit extends from the processor or electronic memory to an electrode so that the wire is completely within the conduit. In still other aspects of the devices described above, the first and second wires connecting the electrodes to the processor or electronics each include slack between the electrode and the processor. In one aspect, the slack is located in a portion of each wing that is configured to bed or flex. In another aspect, the slack is a portion of the wire within the wing and at least partially coiled about the first or the second electrode. In still other aspects, the slack is provided by a portion of the wire formed into a coil, a wave pattern, or a sinusoidal pattern along its length the connection point on the electronics to the connection point on the electrode.

In still other alternatives, the devices described above may be applied to any of a wide variety of conventional physiological data monitoring, recording and/or transmitting devices. Any of the improved adhesion design features and aspects may also be applied to conventional devices useful in the electronically controlled and/or time released delivery of pharmacological agents or blood testing, such as glucose monitors or other blood testing devices. Additional alternatives to the devices described may include the specific components of a particular application such as electronics, antenna, power supplies or charging connections, data ports or connections for down loading or off loading information from the device, adding or offloading fluids from the device, monitoring or sensing elements such as electrodes, probes or sensors or any other component or components needed in the device specific function. In still other aspects, the electronic component in any of the above devices is an electronic system configured for performing, with the electronic signals of the mammal detected by the electrodes, one or more or any combination of or the following electronic functions: monitoring, recording, analyzing, or processing using one or more algorithms electronic signals from the mammal. Still further, any of the devices described above may include appropriate components such that the device is used to detect, record, process or transmit signals or information related to signals generated by a mammal to which the device is attached including but not limited to signals generated by one or more of EKG, EEG and/or EMG.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. **1** is a top view of a patch having two wings;

FIG. **1**A is a representative cross-section of an embodiment of the patch in FIG. **1**;

FIG. **1**B is a representative cross-section of another embodiment of the patch in FIG. **1**;

FIG. **1**C is a representative cross-section of another embodiment of the patch in FIG. **1**;

FIG. **1**D is a representative cross-section of another embodiment of the patch in FIG. **1**;

FIG. **1**E is a representative cross-section of another embodiment of the patch in FIG. **1**;

FIG. **1**F is a top view of a patch having three wings illustrating an alternative electrode-electronics-electrode orientation;

FIG. **2**A is a schematic drawing of the electronics contained within a patch;

FIG. **2**B is a schematic drawing of a patch with wiring having slack in the form of undulations between electronics and electrodes;

FIG. **2**C is a schematic drawing of a patch with wiring having slack in the form of a coil between electronics and electrodes;

FIG. **3** is the bottom view of a patch having adhesive thereon;

FIG. **4**A shows a patch as worn by a person rolled to the side;

FIG. **4**B shows a patch as worn by a person playing golf;

FIG. **5**A shows a patch in response to a concave bend of the skin;

FIGS. **5**B and **5**C show a patch in response to a convex bend of the skin;

FIG. **6**A is a bottom view of a patch having a connector between two flaps;

FIG. **6**B is a cross-section of the patch of FIG. **6**A;

FIG. **7**A is a bottom view of a patch having multiple covers forming strips of adhesive;

FIG. **7**B is a cross-section of the patch of FIG. **7**A;

FIG. **8**A is a bottom view of a patching having multiple covers forming strip of adhesive around each electrode;

FIG. **8**B is a cross-section of the patch of FIG. **8**A;

FIGS. **9**A and **9**B show a patch having multiple layers formed thereon;

FIGS. **10**A and **10**B show a patching having multiple layers formed thereon, each layer having multiple patches of adhesive;

FIG. **11** shows a patch having an open cell support;

FIG. **12** shows a patch having an annular open cell support;

FIG. **13**A shows a patch having a protective shell thereon; and

FIG. **13**B shows a cross-section of the patch of FIG. **13**A.

DETAILED DESCRIPTION

The following device features and design elements can be implemented into any device being adhered to the human body for a long-period of time, typically greater than 24 hours. As an example, the following device features and design elements can be used for long-term adhesion of a cardiac rhythm monitoring patch ("patch") to the chest of a person.

Referring to FIGS. **1** and **1**A, a patch **100** for long term adhesion includes a housing **102**. The housing **102** can be formed from any flexible, durable material, such as a biocompatible polymer, for example silicone. The housing **102** can include electronic components **108** therein. As shown in FIG. **2**, the electronics **108** can include a printed circuit board **220**, a battery **225**, and a communications port mounted on the printed circuit board **220**. The printed circuit board **220** can include analog circuits **210**, digital circuits **215**, and an activation or event notation button or switch **130**. The electronics **108** can be used, for example, to record continuous physiological signals from a mammal wearing the patch **100**. A system for continuously recording data is described further in co-owned U.S. application Ser. No. 11/703,428, filed Feb. 6, 2007, the entire contents of which are incorporated by reference herein.

As shown in FIGS. **1** and **1**A, wings **104**, **106** can be connected to the housing **102**. The wings **104**, **106** can be integral with the housing **102** and, in some embodiments, can be formed of the same material as the housing **102**. The wings **104**, **106** can be more flexible than the electronic components **108**, which can be substantially rigid. An electrode **124**, **126** can extend through a bottom surface of each wing **104**, **106**. The electrodes can be positioned to detect an ECG of a mammal wearing the patch **100** for processing by the electronics **108**. For example, the electrodes can be more than 2 cm apart, such as more than 3 cm apart, for example at least 6 cm apart. The electrodes **124**, **126** can be integral with the wings **104**, **106** so as to be inseparable from the wings **104**, **106** when the patch is in use.

For a patch **100** that is entirely flexible and can conform, stretch, and adapt to the movement and conditions of the chest underneath the device, adhesive can be placed over the entire surface of the device that is in contact with the body, except for areas where sensors, electronics, or others elements such as electrodes are interacting with the body related to the functioning of the device may be incorporated. Thus, as shown in FIG. **3**, an adhesive layer **166** can coat the bottom of the patch **100** tor attachment to the skin, For a patch **100** in which there may be some areas that are not completely flexible and may not be able to stretch or contract (e.g., the electronics **1**(**8**), adhesive may be excluded from the portion of the patch **100** underneath these areas. Thus, for example, the bottom surface **302** of the housing **102**, which contains the electronics, can remain free from adhesive. As shown in FIG. **1**A, by not coating adhesive on a bottom surface of the housing **102**, the housing **102** can float above the adhered portions, allowing for increased flexibility of the patch, as will be discussed further below. Further, as shown in FIG. **3** the bottom surface of the electrodes **124**, **126** can remain free of adhesive. For example, a ring **362** without adhesive can be formed around each electrode **124**, **126** to separate the electrodes from the adhesive **164**, The adhesive can be, for example, a pressure-sensitive adhesive, such as polyacrylate, polyisobutlene, or a polysiloxane. Alternatively, the adhesive can be a hydrocolloid which advantageously absorbs water.

The wings **104**, **106** and the housing **102** can form a smooth, contiguous outer surface to the patch **100**, As shown in FIG. **1**A, when viewed from the top, the housing **102** and wings **104**, **106** can together form an oblong substantially oval shape, Further, the housing **102** can have a thickness that is greater than the thickness of the wings **104**, **106**. The housing **102** and each of the wings **104**, **106** when viewed in profile, can each form a dome with a height that is greater at the center than at the ends of the respective component, i.e. some or all of the components can be tapered at the ends and/or sides.

The electronics **108** can extend along only a portion of the distance between the electrodes **104**, **106**. For example, the electronics can occupy less than 90% of the distance between the electrodes, for example less than 80%. By having the electronics **108** in a relatively limited space between the electrodes **124**, **126**, the flexibility of the patch **100** can be increased

The housing **102** can provide a watertight enclosure **110** for electronic components **108** of the patch **100**, The electronics **108** can be unattached to the housing **102** such that the electronics **108** are free to move within the watertight enclosure **110**. Allowing the relatively rigid electronics **108** to move freely within the flexible housing **102** advantageously enhances the overall flexibility of the patch **100**, The wings **104**, **106** can each have a watertight enclosure **114**, **116** formed therein, which can be contiguous with the watertight enclosure **110** of the housing **102**.

Wiring **120** or other suitable electrical connections can connect the electrodes **124**, **126** with the electrical components **108** of the housing. In some embodiments, as shown in FIGS. **1**B-**1**E, the contiguous nature of the enclosure **110** and the enclosures **114**, **116** allows the wiring **120** to extend within the patch **100** from the electrodes **124**, **126** to the electronic components **108**. In other embodiments, one or more channels, tubes, or conduits are provided between the housing **102** and the wings **104**, **106**, to provide space for the wiring **120**. The tube or channel may be straight or curved. In use, the wire **120** positioned in the enclosures **110**, **114**, **116** or in the tube or channel may move relative thereto in order to remain flexible within the housing. In one aspect, the flexible channels or tubes are formed within the device housing so that the housing, as it is being stretched, does not affect the ability of the components, such as wires, that may connect more rigid structures, to move or elongate.

As shown in FIG. **1**, the wire **120** is straight with a direct line of connection between the electrodes **124**, **126** and the

electronics **108**. FIG. **1** illustrates an embodiment where the length of the wires **120** connecting the electrodes **124**, **126** to electronics **108** are about the same distance as the spacing between the electrode connection point on electronics **108** and the electrodes **124**, **126**. FIG. **1**F also illustrates a straight line type connection where wire **120** length is nearly the same as the spacing between the electronics **108** and the electrodes **124**, **126**. However, as a patient moves, the patch **100** flexes along with patient movement. As shown in FIGS. **4**B and **5**C, patch flexion may be severe and is likely to occur during long term monitoring. In order to address the possible dislocation or breakage of the wire **120**, the length or shape of the wire **120** may be selected to permit patch flexion to occur with little risk of wire **120** pulling from the electrode or electronics. Numerous alternatives are possible to compensate for patch flexion. Exemplary confirmations include undulations or zig-zags **231** as shown in FIG. **2**B, coils **233** as shown in FIG. **2***e*, or a configuration that partially or fully wraps around an electrode. In some embodiments, other components, such as the circuit hoard or electrodes, can alternatively or additionally contain additional length to help accommodate stretch or displacement. When the patch **100** is attached to a mammal, the slack in the wiring **120** allows the patch **100** to flex while not placing stress on the wiring **120**.

While the illustrated embodiments of FIGS. **1**A-**1**D show only two wings and show the electrodes and electronics in a direct line in a approximate 180 degree alignment of electrode **124** to electronics **108** to electrode **126**), other configurations are possible. For example, as shown in FIG. **1**F, the wings **104**, **106** are arranged in an orientation less than 180 degrees. In the illustrated embodiment, the angle formed by the electrodes and the electronics is about 135 degrees. Other ranges are possible so long as electrode spacing is provided to permit ECG monitoring. The orientation of the wings **104**, **106** to the housing **102** also illustrates the use of an additional adhesive tab **105**. Tab **105** is shown as a semicircular extension of the body **102**. The bottom of tab **105** can include adhesives as described herein and is used to provide additional anchoring of the patch to the patient. The tab **105** may be formed in any of a number of different shapes such as rectangles, ovals, loops or strips. Further, in some embodiments, the tab **105** can function similar to a wing, e.g., include an electrode therethrough that connects to the electronics **108**.

Referring to FIGS, **1**A-**1**D and **2**B-**2**C, a hinge portion **194**,**196** in the patch **100** can extend between each electrode **124**, **126** and the electronics **108**. The hinge portions **194**, **196** can have a thickness less than the thickness of surrounding portions of the patch **100**, For example, if the hinge portions **194**, **196** are in the wings **104**, **106**, then the thickness can be less than adjacent portions of the wings. Likewise, the hinge portions **194**, **196** can have a width less than adjacent portions of the patch **100**, e.g., less than adjacent portions of the wings **104**, **106**. Alternatively, the hinged portion can be formed by the adjunct between a rigid portion, i.e. the electronics **108**, and a more flexible portion, The hinged portion allows the patch **100** to bend between the housing **102** and wings **104**, **106** to compensate for any movement caused by the patient. As shown in FIGS. **2**B and **2**C, the slack in the wiring **120** can be placed at or proximal to the hinge portions **194**, **196** to allow for bending at the hinge portions **194**, **196** without pulling or breaking the wiring **120**.

Referring to FIGS. **4**A and **4**B, having adhesive on the bottom of the patch **100** except in the areas substantially around the electrodes and directly underneath the housing **102** can create a floating section **455** over the skin of the mammal to which the patch **100** is attached. The floating section **455** can house the more rigid or less flexible electronic components while the flexible wings **104**, **106** can be adhered to the skin and provide the flexibility necessary to hold the patch **100** in place. As a result of this selective use of adhesive areas and non-adhesive areas, the limitation on device flexibility imposed by the less flexible floating section can he mitigated or reduced by hounding the floating section with one or more adhered flexible areas. The flexible sections can thus adhere to the body if the underlying portion of the body is stretched and/or contracted while the floating section is free to move above the skin, for example if the person wearing the device rolls over (as shown in FIG. **4**A) or is involved in activities that can otherwise cause movement of the skin (as shown in FIG. **4**B).

Referring back to FIGS. **1**B-**1**E, each wing **104**, **106** can include a material layer **214**, **216** between the adhesive **164**, **166** and the wings **104**, **106**, The material layer **214**, **216** can be, for example, a polyester layer. The material layer **214**, **216** can be attached to the patch **100** with a layer of adhesive **204**, **206**, The adhesive **204**, **206** can be the same as the adhesive **164**, **166** or different. For example, the adhesive **204**, **206** could be a silicone adhesive. The material layer **214** can serve as a barrier to prevent diffusion or migration of adhesive components, such as a tackifier, from the adhesive **164**, **166** into the wings **104**, **106** or housing **102**. The material layer **214** can thus advantageously serve to maintain the strength of the adhesive **104**, **106** over time.

Referring still to FIGS. **1**B-**1**E, the patch **100** can further include a first flap **154** connected to the first wing **104** and a second flap **156** connected to the second wing **106**. The flaps **154**, **156** can both extend from a position on the wings **104**, **106** medial to the electrodes to a position below the housing **102**, such as below the electronics **108**. The flaps **154**, **156** can remain unattached to the housing **102**. As a result, gaps **144**, **146** can be formed between the flaps **154**, **156** and the housing **102**. The gaps can provide additional "floating" for the housing **102** and the relatively rigid components **108** contained therein.

In some embodiments, shown in FIG. **1**B, the flaps **154**, **156** can be attached to the wings **104**, **106** with adhesive **134**, **136**. The adhesive **134**, **136** can be the same as the adhesive **164**, **166** or different. For example, the adhesive **134**, **136** could be a silicone adhesive. In other embodiments, shown in FIGS. **1**C-**1**E, the flaps **154**, **156** can be integral with the wings **104**, **106**. For example, the flaps **154**, **156** can be solvent welded to and/or formed during the molding process of the wings **104**, **105** such that hinges **194**, **196** form below the wings **104**, **106**. Additionally or alternatively, one or more of the flaps **154**, **156** may be separably attached to the wings **104**, **106**. In some embodiments, shown in FIGS. **1**B and **1**C, the materials making up the flaps **154**, **156** can extend all the way to the lateral edge of the patch **100**. In other embodiments, shown in FIG. **1**D, a flap can extend on each side of the electrodes, i.e. one flap can extend medially and the other laterally. In some embodiments, the lateral and medial-extending flaps are part of the same annular flap. In other embodiments, shown in FIG. **1**E, the flaps and materials making up the flaps extend only from a position medial to the electrodes underneath the housing.

The Flaps **154**, **156** may be positioned in virtually any relationship to the adhered flexible area such that, when attached in use, the attachment of the flap or flaps effectively counteracts the expected external forces acting on the device, specifically those forces that may dislodge the adhered flexible areas. Further, in embodiments such as that

shown in FIG. **1**F where there are more than two wings, there can be a flap corresponding to each additional wing.

The adhesive layers **164**, **166** can coat all or a portion of the bottom of each of the flaps **154**, **156**. In some embodiments, the adhesive **164**, **166** extends continuously from the bottom surface of the wings **104**, **106** to the bottom surface of the flaps **154**, **156**, except for areas proximate to the electrodes **124**, **126**. Further, the top surface of the flaps **154**, **156**, i.e. the surface closest to the housing **102**, can remain free of adhesive to ensure that the housing **102** remains floating. In some embodiments, the only portion of the patch **100** including adhesive for adhesion to the skin can be the flaps **154**, **156**.

Referring to FIGS, **5**A-**5**C, the naps **154**, **156**, can provide hinge-like behavior for the patch **100**, Thus, as shown in FIG. **5**A, if the skin **501** is stretched or bent in a concave manner, the gaps **144**, **146** between the flaps **154**, **156** and the housing **102** can approach zero such that the patch **100** can sit substantially flat on the skin **501**. As shown, the hinge portions **194**, **196** between the housing **102** and wings **104**, **106** can provide additional flexibility for concave bends by flattening as the patch **100** is stretched. In contrast, as shown in FIGS. **5**B and **5**C, as the skin **501** is bent in an increasingly convex manner, the gaps **144**, **146** between the flaps **154**, **156** and the housing **102** can increase, thereby allowing the flexible wings **104**, **106** to remain adhered to the skin and the rigid housing **102** to float above skin. As shown, the hinge portions **194**, **196** between the housing and the wings **104**, **106** can provide additional flexibility for convex bends by folding inward as the patch **100** is bent.

When placed substantially flat on the skin **501**, the patch **100** can have a height that extends no more than 2 cm off of the skin, such as no more than 1.5 cm off of the skin, when lying flat on the patient and no more than 4 cm, such as no more than cm off of the skin when floating above the skin. The relatively low height of the patch **100** can enhance long-term adhesion by reducing the potential for the patch] **00** to snag or rip off of the skin.

Advantageously, the flaps **154**, **156** can function as anchors for adhesion that mitigates shear force. The flaps **154**, **156** can provide a different direction for the acute and chronic forces being experienced by the device due to stretching, contraction, or torsion to be spread out over both the flap as well as the flexible adhesive areas. Further, by pre-aligning the orientation of the floating section, adhered flexible area and the flaps, the device may be better able to tolerate (i.e., remain attached to the body and in use) and/or tailor the interaction with the forces acting on the device in order to better withstand the acute or chronic forces being experienced by the device. Tailoring the response of the device to the expected forces is one

Because the flaps can be used to counteract forces acting on a particular device, it is to be appreciated that the dimensions, flexibility, attachment technique, and/or orientation between a flap and another component may vary depending upon the purpose of a particular flap. Accordingly, a flap may have the same or different characteristics from another flap or component of the device. In one aspect, at least one flap is more flexible that the other flaps in a particular device. In another aspect, each of the flaps has similar flexibility. In still another aspect, at least one flap is more flexible than the device component to which it is attached or from which it originates. In still another aspect, at least one flap is less flexible than the device component to which it is attached or from which it originates.

Referring to FIGS. **6**A and **6**B, in one embodiment, the flaps **154**, **156** may be augmented by a connector segment **607** used to join the flaps together. The connector segment **607** can extend below the housing **102**, but remain unattached to the housing **102**. As shown in FIG. **6**A, the flaps **154**, **156** and the connector **607** can together form a butterfly shape. In one embodiment, the connector segment **607** and the flaps **154**, **156** are formed from a single piece of material. The connector segment **607** can be made of the same material as the flaps **154**, **156** or of different material. In one embodiment, the bottom surface of the connector is covered with adhesive. In another embodiment, the bottom surface of the connector does not include any adhesive. Further, as shown in FIG. **6**B, the connector segment **607** can be thicker in the middle, under the housing **102**, than near the edges, i.e., closer to the electrodes. The variable thickness can help prevent the connector segment **607** from capturing moisture thereunder. The connector segment **607** can advantageously prevent the device from flipping when attached to the patient

The connector segment **607** can include one or more holes **614**, **616**. In some configurations, the connector segment may trap moisture and/or inadvertently stick to the body. The holes **614**, **616** can advantageously minimize the potential for undesired sticking or moisture collection. The size, shape and placement of the holes mitigate or reduce the collection of moisture and/or undesired adhesive still providing a connector with sufficient structural integrity (i.e. the connector allows the flaps to be connected to one another in order to prevent them from folding). Additionally or alternatively, the connector holes could also be made to preferentially allow forces to be distributed along certain axes of the connector in order to further maximize the ability of the device to adhere tong-term in the face of significant acute and chronic forces due to stretching, contraction, and torsion.

Adhesive can be selectively applied to the connector and/or naps to provide the desired body attachment locations depending upon the specific use of the device. For example, one piece of material including flaps and the connector can be adhered along two or more edges and/or with adhesive only covering certain areas, In another aspect, at least a portion of the skin-contacting surface of the unitary nap connector structure does not include any adhesive. Additionally or alternatively, the connector segment incorporating the flaps may be integral parts of the larger device housing (e.g. could be molded as part of the device housing or enclosure).

In some embodiments, the patch **100** can include one or more release liners to cover parts of the adhesive prior to adhesion. As is particular to devices having multiple adhesive areas and/or multiple adhesive components (i.e., flaps and flexible sections), the manner of applying the device may be specifically detailed in order to ensure that the device and the adhesive portions are properly engaged. In one particular aspect, the release liners are removed in a particular order to minimize the likelihood that the device adhesive is misapplied. For example, a portion of the adhesive may be exposed first and used to affix the device to the body, Thereafter, a second set of adhesive liners may be removed to expose and affix one or more flaps to the body, A stepwise adhesive exposure method may be implemented during device application such that elements, such as the one or more flaps do not fold on themselves, for example.

Breaking up the areas in which the adhesive is used to adhere the device, whether it be splitting it up to rigid areas, to create flaps, to create connector segments with holes, of any of the other techniques described above may also have benefits in terms of preventing moisture bridges that could act as conducting pathways between electrical sensing ele-

ments, such as electrodes. Bridges of moisture could short-circuit electrical connections and/or prevent the proper functioning of the device, particularly if the device has an electrical function, such as sensing via electrodes.

In some applications, a long-duration patch may experience excessive forces due to acute (quick and/or rapid) or chronic (slow and/or prolonged) contraction, stretching, or torsion. In such applications, the hinge points between a floating rigid section and flexible adhered sections may be modified in order to align with and counteract or mitigate the predominant direction of the force acting on the patch. In some device situations or configurations, the strength and direction of the acute or chronic force may be so strong that the forces imparted on the device adhesive surfaces or components may be distributed differently in addition to or as an alternative to the hinge described above.

Further, the device construction can be made in such a way that the housing is fashioned so that the axes of the housing are structured and placed along or against the direction of various forces, possibly during certain states, such as sleeping, so that the device itself can help counteract these forces and improve long-term adhesion.

Advantageously, the patch described herein can provide long-term adhesion to the skin. Having the various flexible portions and/or hinged portions can compensate for stressed caused as the skin stretches or bends, while allowing the rigid portion to float about the skin. As a result, the devices described herein can adhere to the skin substantially continuously tor more than 24 hours, such as greater than 3 days, for example, greater than 7 days, greater than 14 days, or greater than 21 days.

Another mechanism for adhering a patch to the skin long-term is described with respect to FIGS. **7-10**. As shown in the embodiments of FIGS. **7-10**, one or more parts of the patch are used in a temporary fashion in order to improve adhesion. The adhesive used in the embodiments described below can include a hydrocolloid or a pressure-sensitive adhesive, such as polyacrylate, polyisobutylenes, or polysiloxane.

In one embodiment, shown in FIGS. **7**A and **7**B, the patch **700** can be surrounded with an adhesive **760** having multiple covers **701**, **703**, **705** thereon that can be peeled away in a sequence to expose strips of adhesive **760** underneath. The covers **701**,**703**,**705** can be concentric with one another and be configured to be pulled off separately and sequentially starting from the inside of the patch **700**. Each additional exposed area of adhesive **760** can increase the adhesion life of the patch **700**. Although only three covers are shown in FIG. **7** A, other numbers, such as **2**, **4**, **5**, or more are possible. Further, each electrode **124**, **126** of the patch **700** can include a barrier **714**,**716** to protect the electrodes **124**, **126** from shortage.

In another embodiment, shown in FIGS. **8**A and **8**B, each electrode **124**, **126** can be surrounded by a patch of adhesive **864**, **866**. Accordingly, a set of covers **801**, **803**, **805**, **807** can be positioned sequentially around each of the electrodes **124**, **126** over the adhesive **864**, **866**. The covers **801**, **803**, **805**, **807** can be concentric with one another and be configured to be pulled off sequentially starting from the inside. Each additional exposed strip of adhesive **864**, **866** can increase the adhesion life of the patch **100**. Although only four covers are shown in FIG. **8**A, other numbers, such as 2, 3, 5, or more are possible. Further, each electrode **124**, **126** of the patch **800** can include a barrier **814**, **816** to protect from shortage.

Referring to FIGS. **9**A-**9**B, in other embodiments, shells or layers **901**,**902**,**903** can extend over all or a portion of the patch **900**. Each layer **901**, **902**, **903** can include a strip of adhesive **962** on the bottom surface and an adhesion guard **982** protecting the adhesive. As shown in FIG. **913**, as the patch **900** is worn over a period of time, the layers **901**, **902**, **903** can be sequentially removed. As a new layer is exposed, the adhesive guard **982** of that layer can be peeled away such that the adhesive **962** of the new layer can be used to adhere the patch **900** to the skin, In a similar embodiment, referring to FIGS. **10**A-**10**B, each of the layers **1001**, **1002**, **1003** can include multiple portions of adhesive to help adhere the layer to both the skin and the patch itself. As with the embodiments of FIGS. **7-8**, the number of layers in the embodiments of FIGS. **9** and **10** can vary. For example, there can be 2, 3, 4, or 5 or more layers.

In some embodiments, the layers or covers of the embodiments described herein can be added to the device over time to improve adhesion. Further, the multiple layers or covers of the embodiments described herein can be partially overlapped. Further, in some embodiments, the strips of adhesive can be overlapped.

Advantageously, the use of multiple covers or layers can assist in the adhesive performance of a base or core device because the added surface area or adhesive force of the combined outer layer aids in preventing layer pull away and/or may act to spread forces being experienced away from the core device by spreading those forces over a larger area.

Referring to FIGS. **11** and **12**, an open cell structured support **1330** or porous foam can be used to support a more rigid or less flexible portion **1302** of the patch **1300**, As shown in FIG. **11**, the open cell structured support **1330** can fully fill an area below the rigid portion **1302**. Alternatively, as shown in FIG. **12**, the open cell structured support **1330** can be an annular shape or have some other configuration that includes spaces between adjacent portions of the support. The open cell structured support **1302** may be attached to both the skin and to the rigid portion, to only the rigid portion, or to only the skin. Because of the open cell structure of the support, the flexible movement of the skin can be absorbed by the structure entirely or partially such that the rigid portion does not impact or has a reduced impact on the ability of the device to accommodate movement and remain affixed. In addition, the open cell support may have a thickness selected to enhance patient comfort so that the more rigid portion of a device does not push against the skin. In one aspect, the open cell structure is a biocompatible foam material. In another aspect, the open cell material is positioned between an electronics module on the device and the skin when worn by a patient. The open cell support can advantageously absorb fluids to keep the electrodes from shorting.

Referring to FIG. **13**, the patch can have a shell design. Adhesive can be placed on the perimeter edge of the bottom ring. The circuit board and electrode unit can be dropped into the bottom ring, and a shell can be dropped on top of the circuit board and electrode. The perimeter adhesive can create a watertight chamber therein.

The shape of a particular electronic device embodiment may vary. The shape, footprint, perimeter or boundary of the device may be a circle or circular (see FIG. **13**A), an oval (see FIGS. **1**A, **2**A), a triangle or generally triangular (see FIG. **1**F) or a compound curve. Examples of a device embodiments having a compound curve shape are shown in FIGS. **2**B, **2**B, **3**, **6**A, **7**A, and **8**A. In some embodiments, the compound curve includes one or more concave curves and one or more convex curves. FIG. **3** illustrates a device having a convex surface along the top (where reference **102**

indicates), a concave surface along the bottom and convex shaped edges around the electrodes **124**, **126**. FIGS. **2**B and **2**C illustrate a device embodiment having a convex shape on either side of the electronics **108** and around the electrodes **124**, **126**. The convex shapes are separated by a concave portion. The concave portion is between the convex portion on the electronics and the convex portion on the electrodes, In some embodiments, the concave portion corresponds at least partially with a hinge, hinge region or area of reduced.

While described in the context of a heart monitor, the device adhesion improvements described herein are not so limited. The improvement described in this application may be applied to any of a wide variety of conventional physiological data monitoring, recording and/or transmitting devices. The improved adhesion design features may also he applied to conventional devices useful in the electronically controlled and/or time released delivery of pharmacological agents or blood testing, such as glucose monitors or other blood testing devices. As such, the description, characteristics and functionality of the components described herein may be modified as needed to include the specific components of a particular application such as electronics, antenna, power supplies or charging connections, data ports or connections for down loading or off loading information from the device, adding or offloading fluids from the device, monitoring or sensing elements such as electrodes, probes or sensors or any other component or components needed in the device specific function. In addition or alternatively, devices described herein may be used to detect, record, or transmit signals or information related to signals generated by a body including but not limited to one or more of EKG, EEG, and/or EMG.

What is claimed is:

1. An electronic device for long-term adhesion to a user, the device comprising:

a housing comprising a physiologic data collection circuit, the housing positioned over a flexible layer extending from the housing, the flexible layer comprising an electrode positioned on the bottom of the flexible layer at a position distal from the housing, wherein the flexible layer comprises a polymer upper layer overlying an electrical connection, the electrical connection extending from the physiologic data collection circuit to the electrode, the polymer upper layer adhered to a polymer lower layer underlying the electrical connection;

a lower adhesive layer positioned on the flexible layer and configured to adhere the electronic device to a user, the lower adhesive layer extending at least partially below the housing; and

wherein the housing is configured to tilt at an angle relative to the lower adhesive layer in response to movement of the user.

2. The electronic device of claim **1**, further comprising a flap extending beneath the housing.

3. The electronic device of claim **1**, wherein the housing is rigid.

4. The electronic device of claim **1**, wherein the housing is configured to remain connected to the flexible layer when the housing is tilted at an angle relative the lower adhesive layer in response to movement of the user.

5. The electronic device of claim **1**, further comprising a hinge portion adjacent the housing.

6. The electronic device of claim **1**, wherein the lower adhesive layer comprises a hydrocolloid adhesive.

7. The electronic device of claim **1**, further comprising a synthetic material layer positioned above the lower adhesive layer.

8. The electronic device of claim **1**, wherein the physiologic data collection circuit is configured to collect cardiac rhythm data from the user.

9. The electronic device of claim **1**, wherein the polymer upper layer extends horizontally away from the housing beyond a boundary of the electrode.

10. The electronic device of claim **9**, further comprising an upper adhesive layer positioned over the polymer upper layer.

11. The electronic device of claim **10**, wherein the upper adhesive layer is positioned above the electrode.

12. The electronic device of claim **11**, wherein the upper adhesive layer extends horizontally away from the housing beyond a boundary of the polymer upper layer.

* * * * *

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(54) **PHYSIOLOGICAL MONITORING DEVICE**

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(58) **Field of Classification Search**
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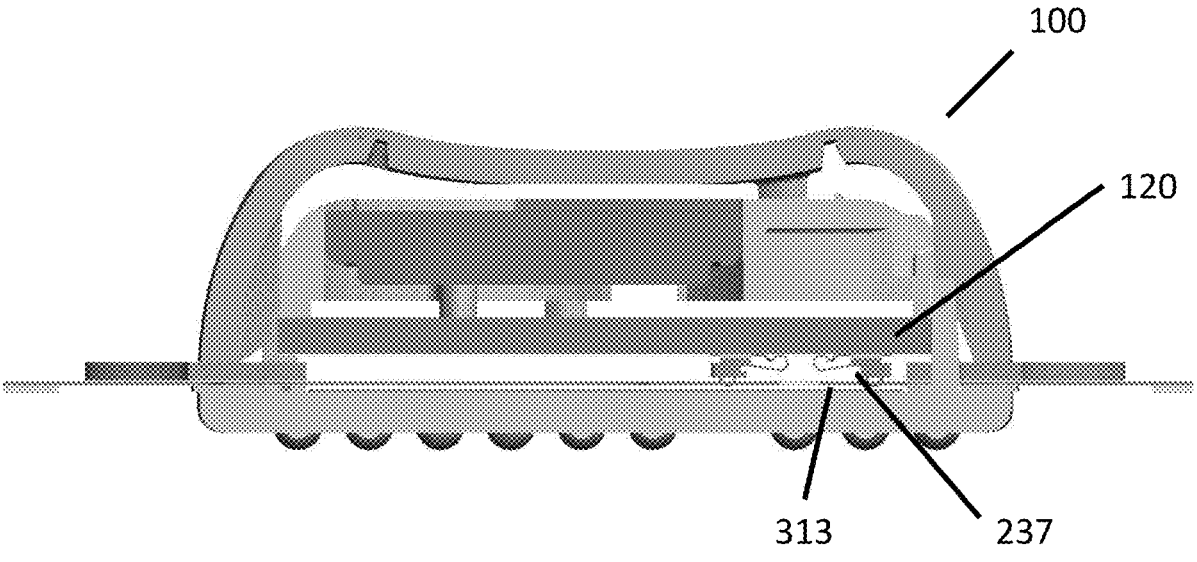
(57) **ABSTRACT**

The present invention relates to a physiological monitoring device. Some embodiments of the invention allow for long-term monitoring of physiological signals. Further embodiments may also allow for the monitoring of secondary signals such as motion.

22 Claims, 17 Drawing Sheets



Related U.S. Application Data

No. 16/786,831, filed on Feb. 10, 2020, now Pat. No. 11,627,902, which is a continuation of application No. 16/397,651, filed on Apr. 29, 2019, now Pat. No. 10,555,683, which is a continuation of application No. 16/006,719, filed on Jun. 12, 2018, now Pat. No. 10,271,754, which is a continuation of application No. 14/162,656, filed on Jan. 23, 2014, now abandoned.

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USPC 438/50–51, 53
See application file for complete search history.

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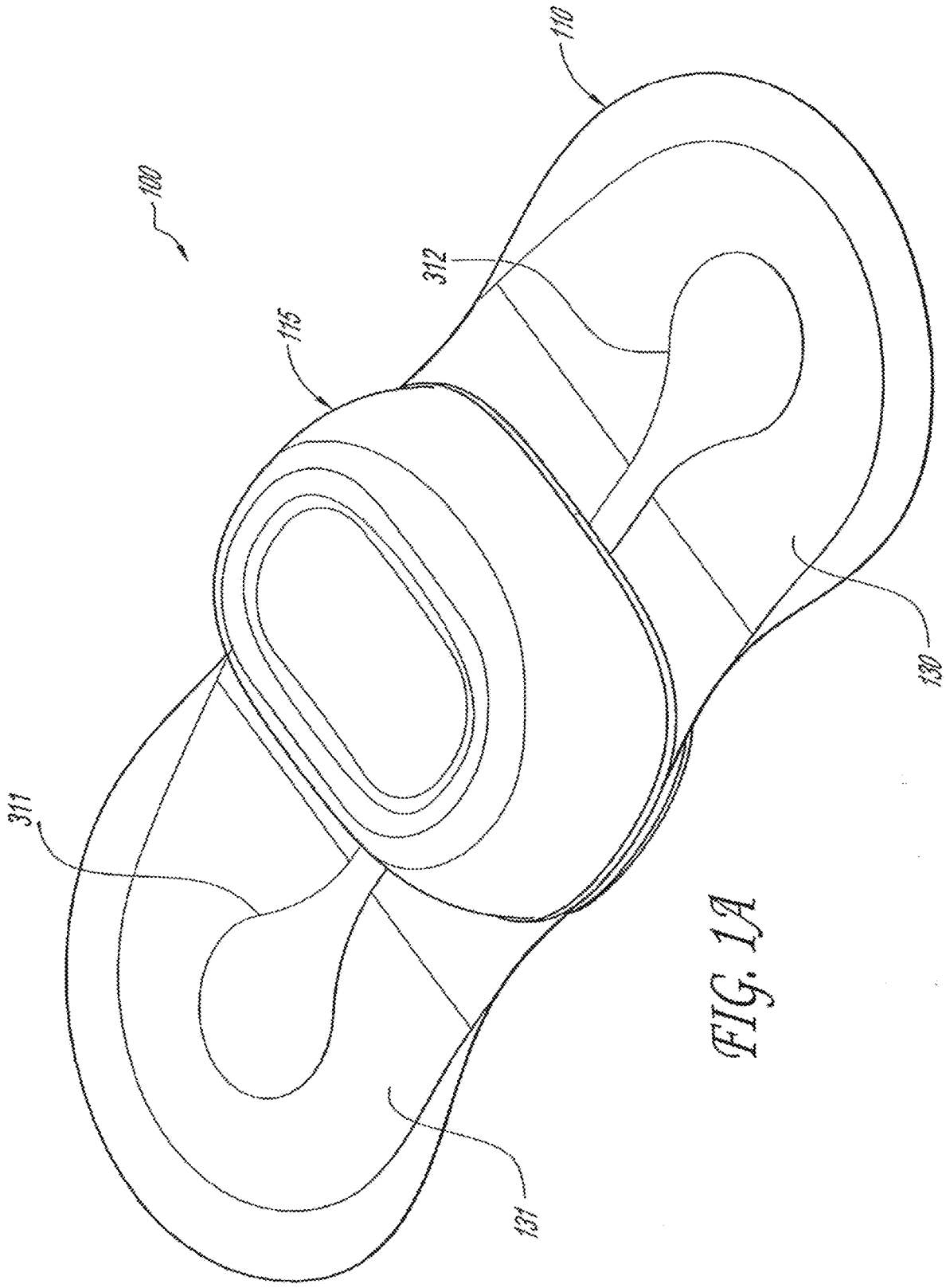

FIG. 1A

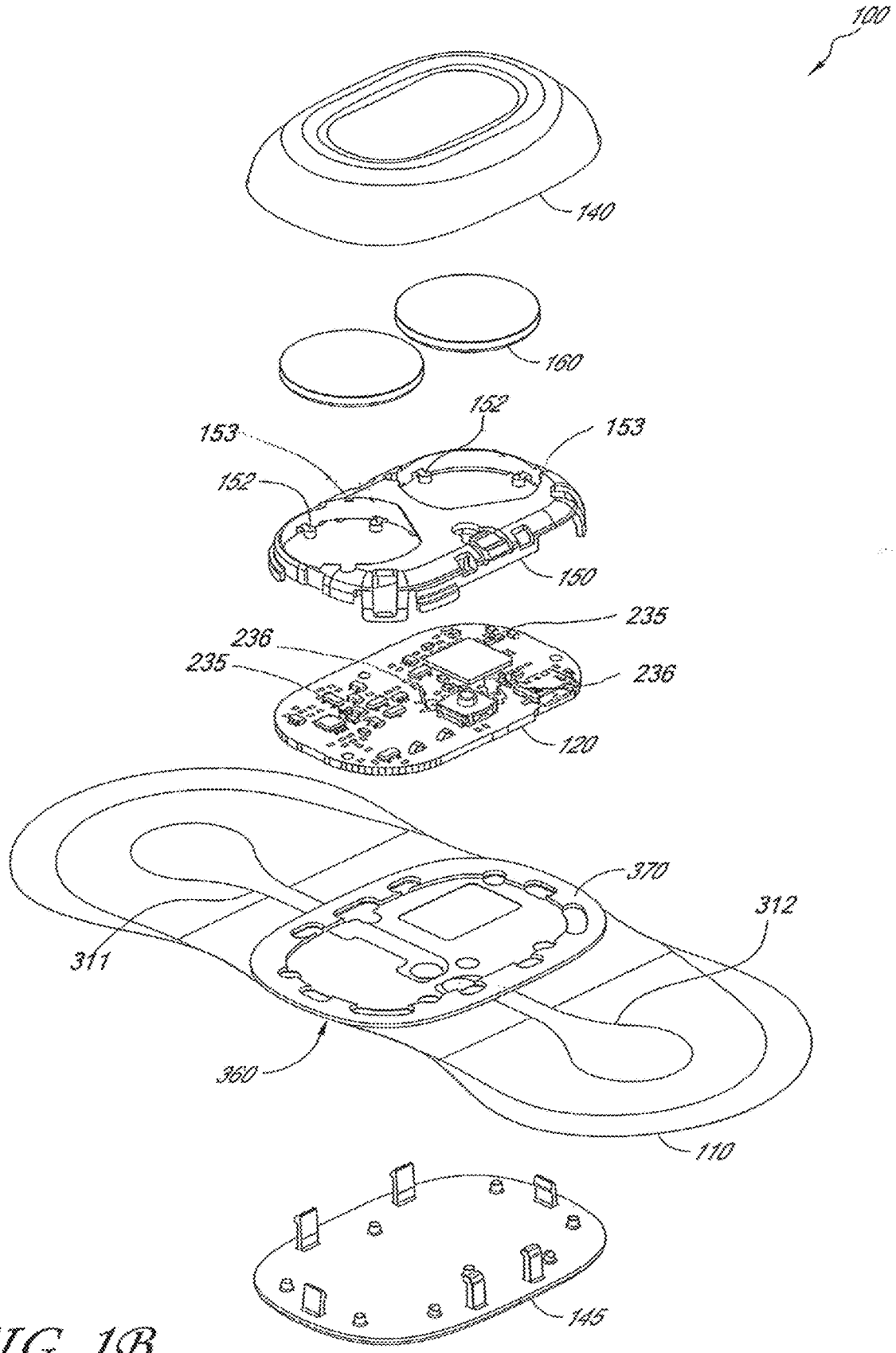
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FIG. 1B

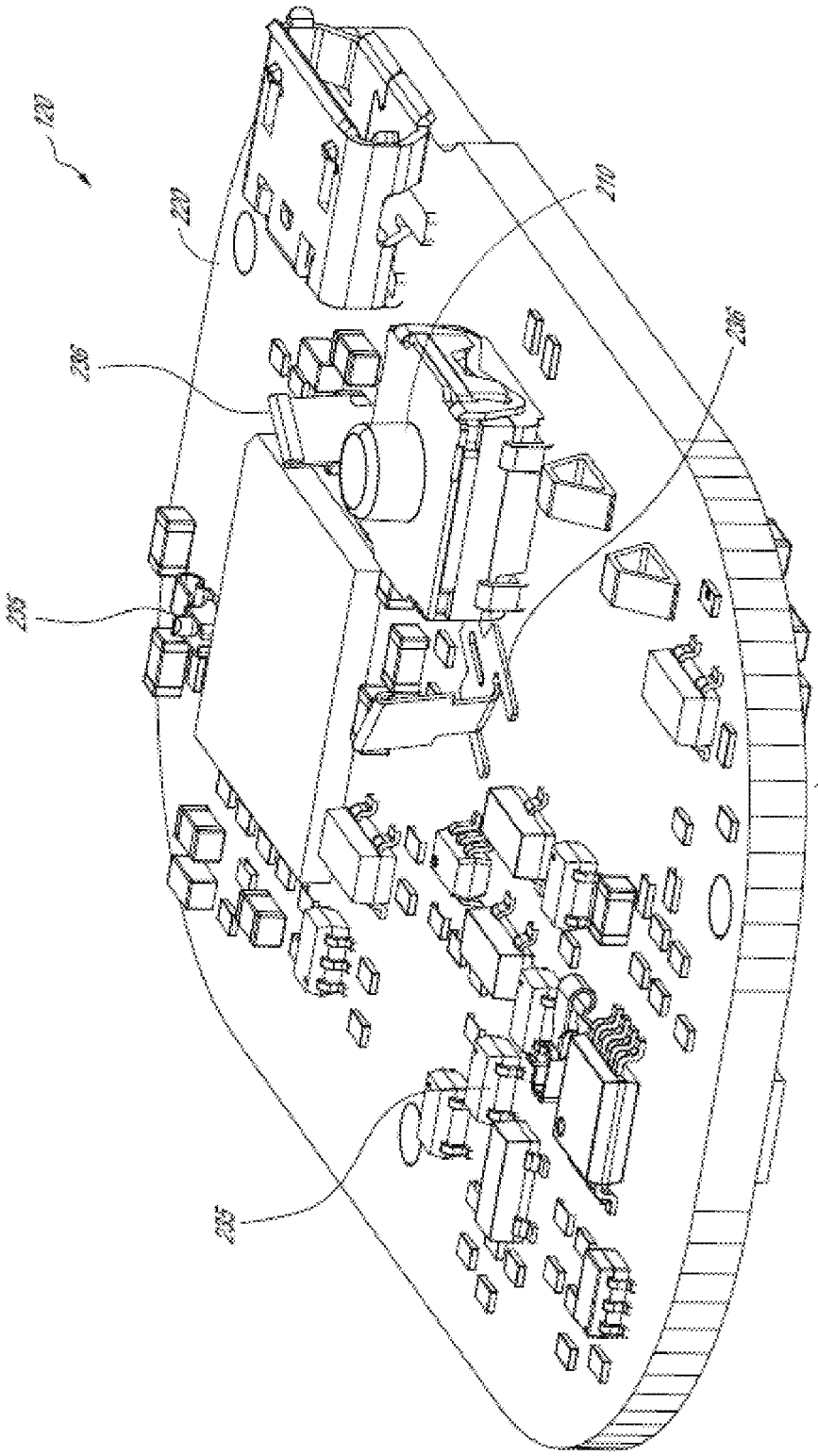
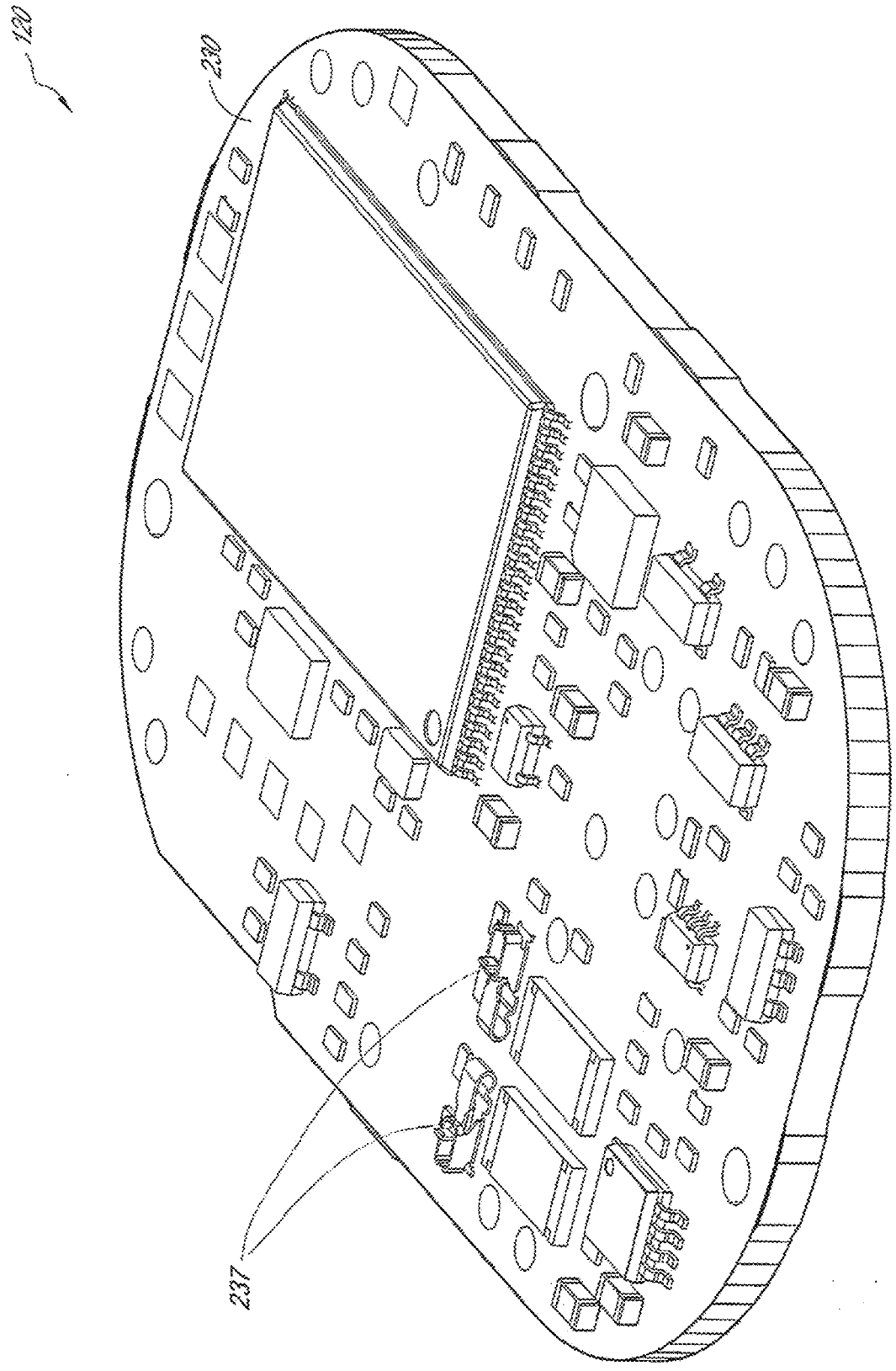


FIG. 2A



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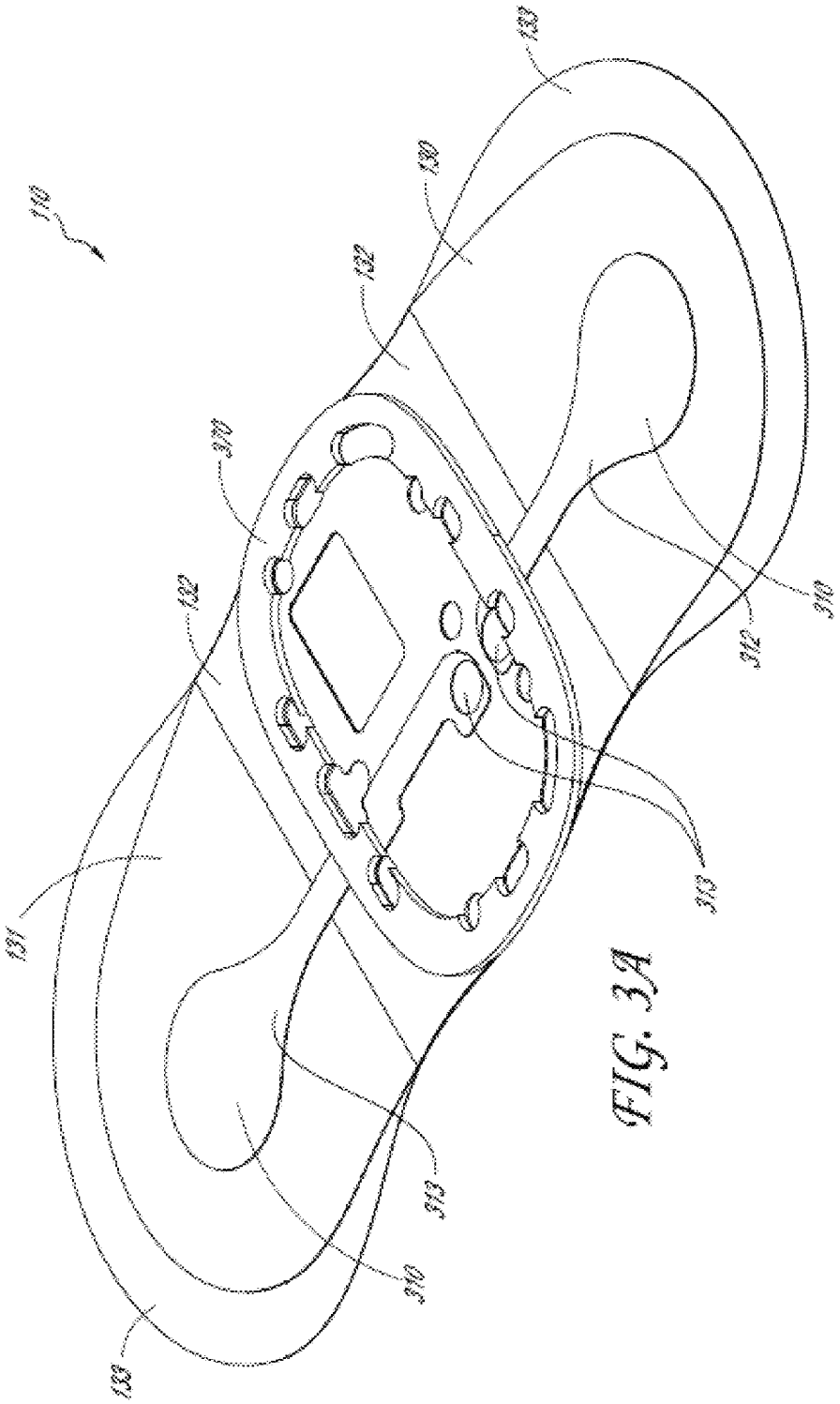
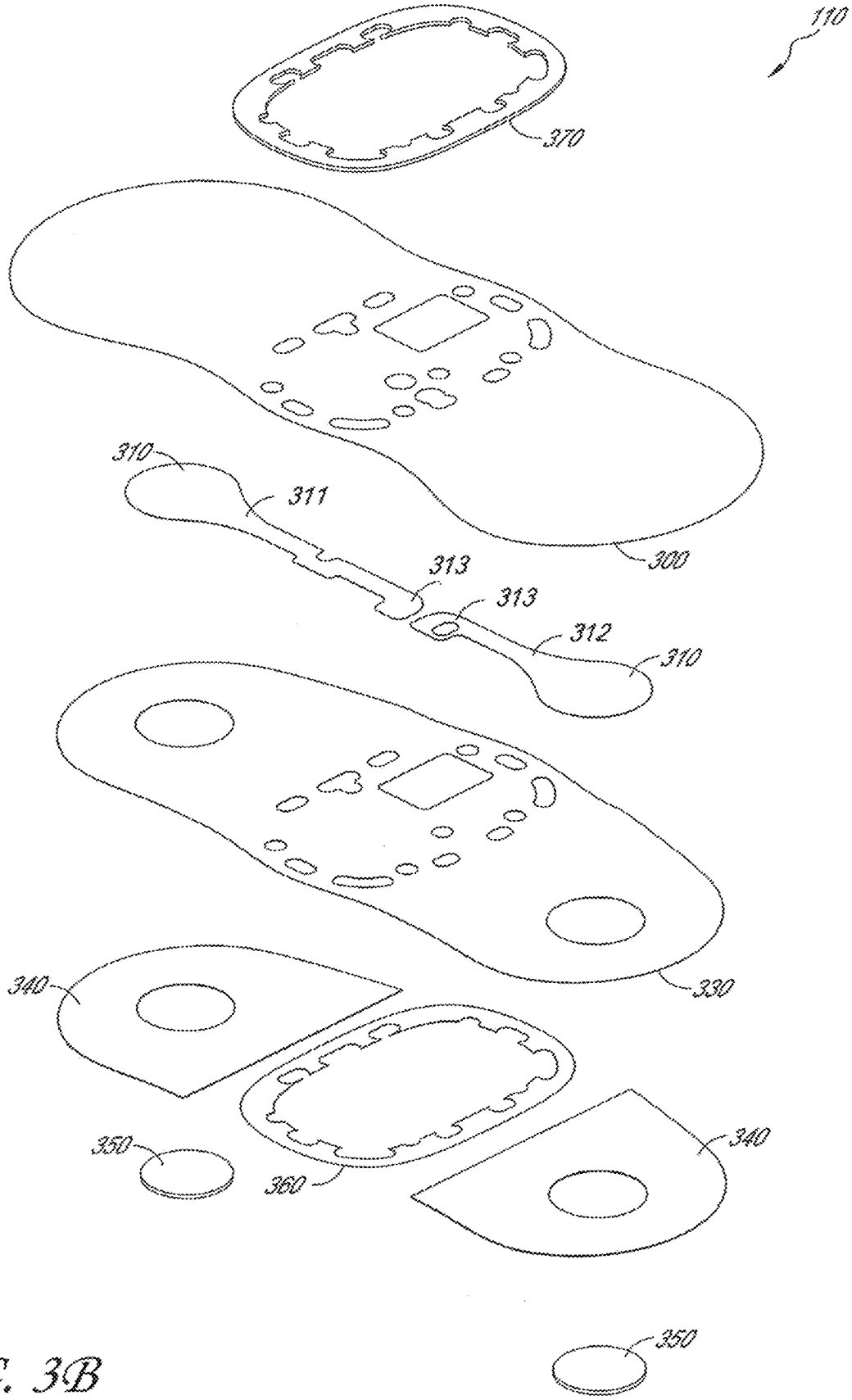


FIG. 3A



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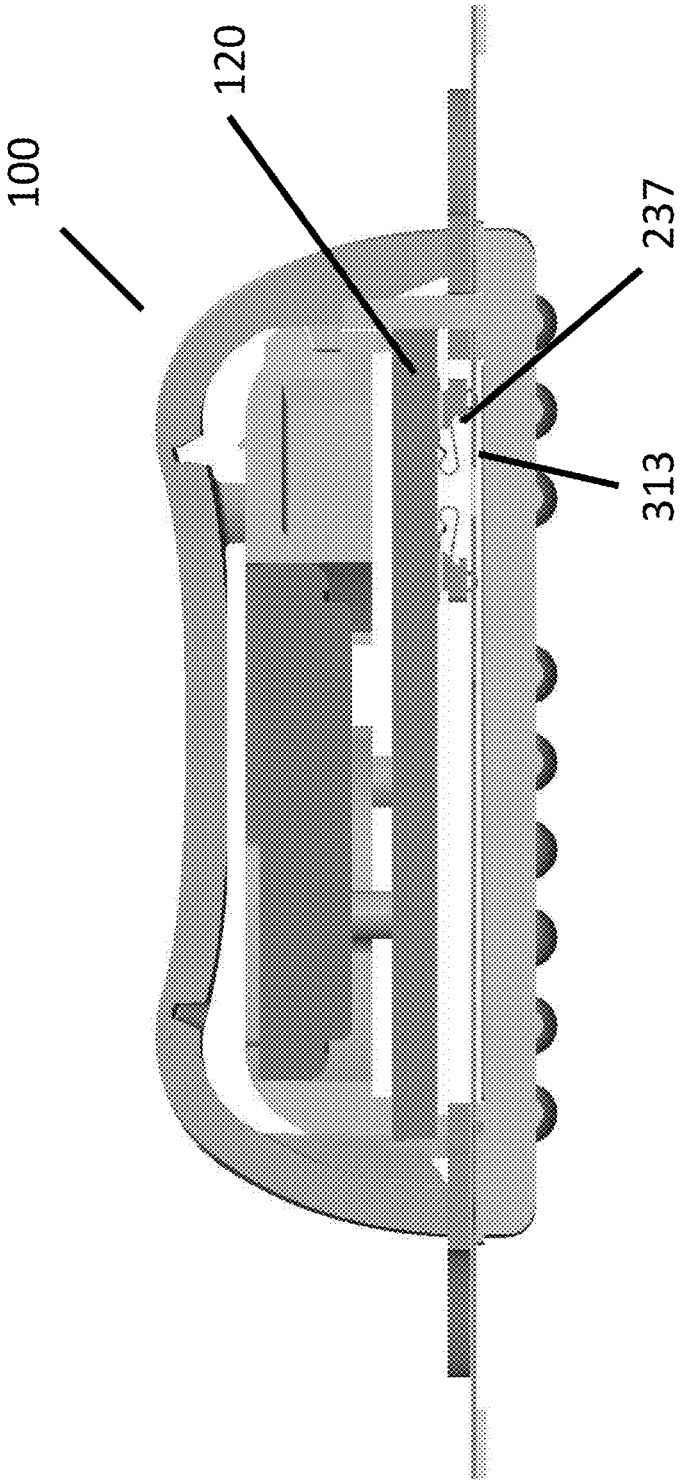


FIG. 3C

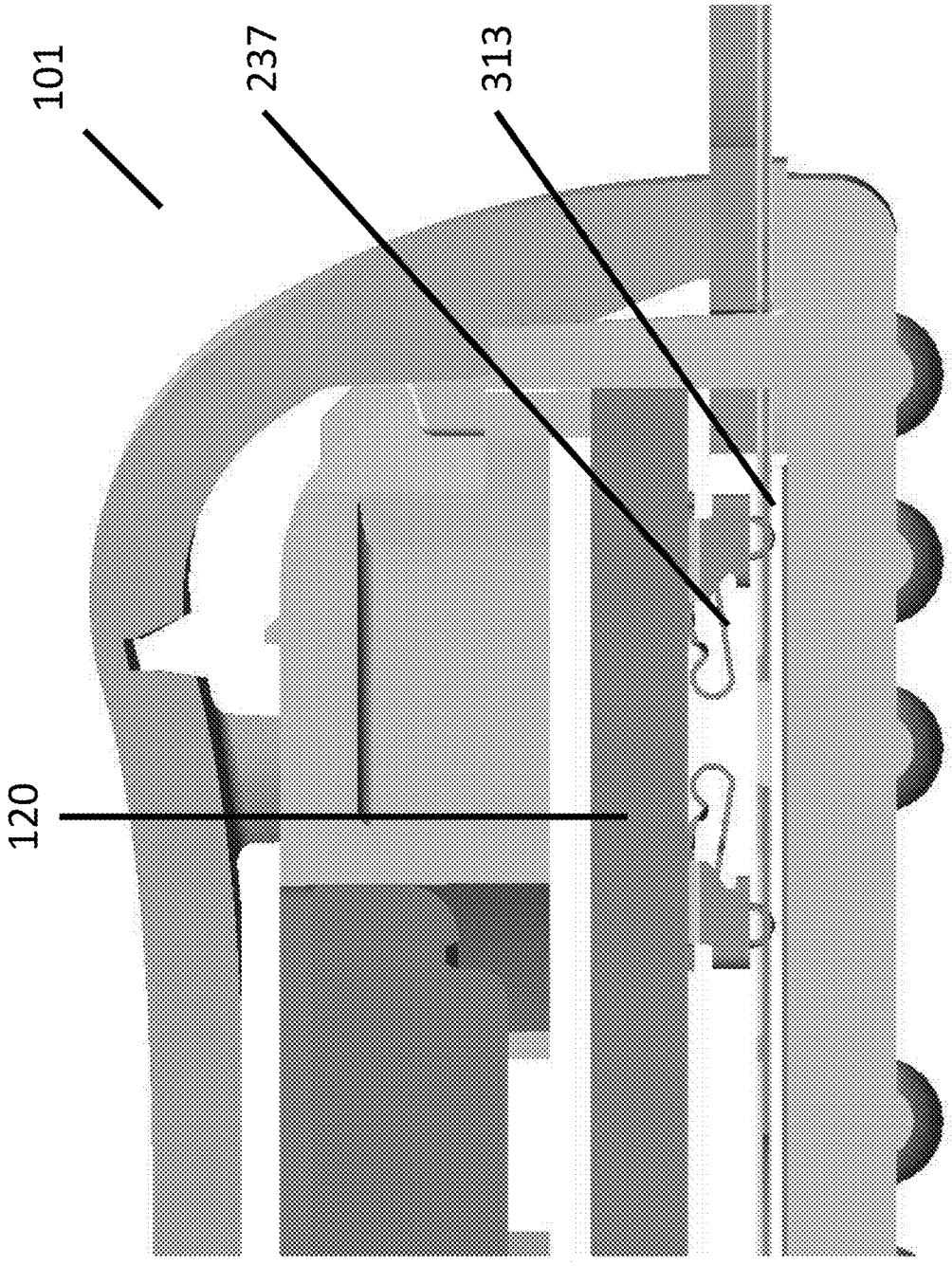


FIG. 3D

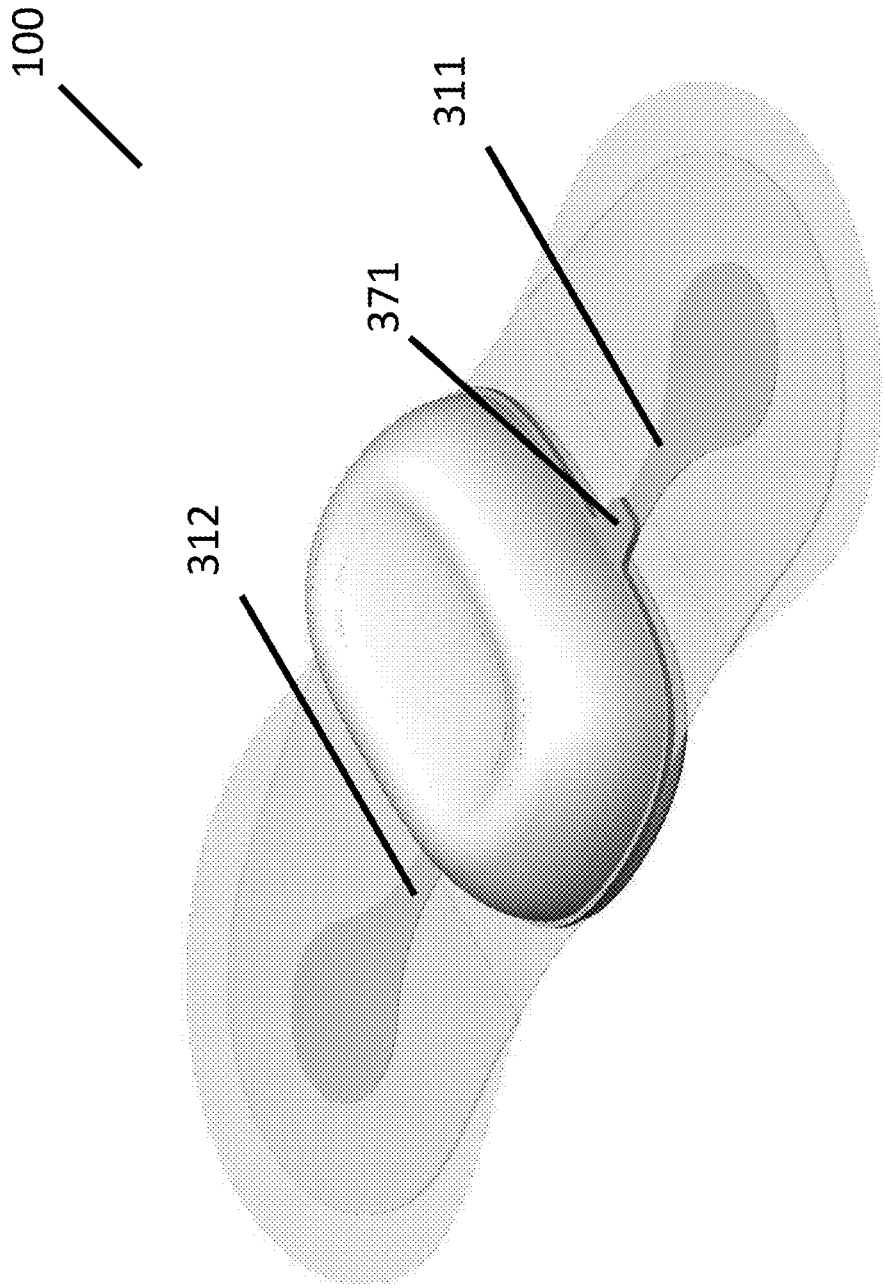


FIG. 3E

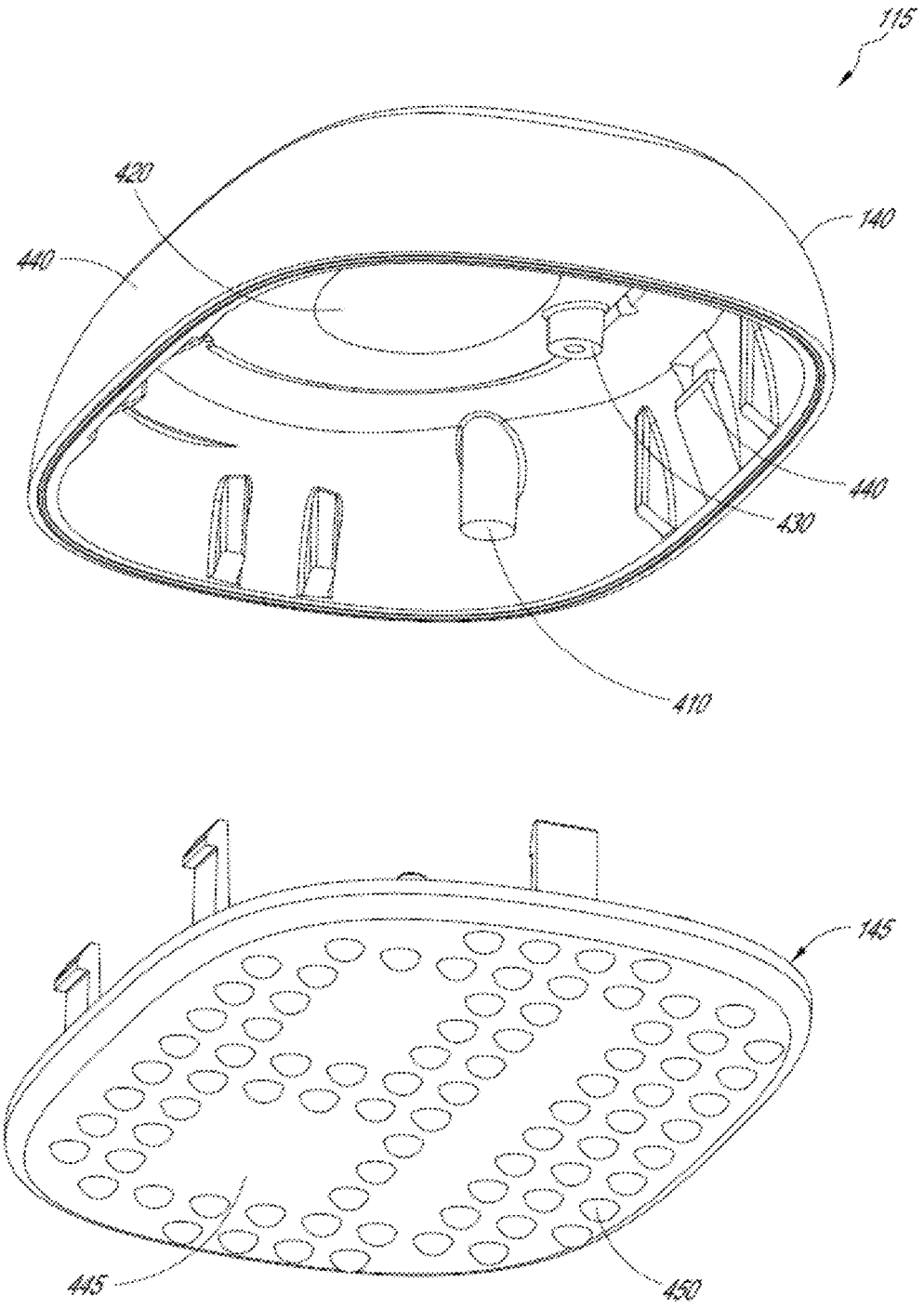
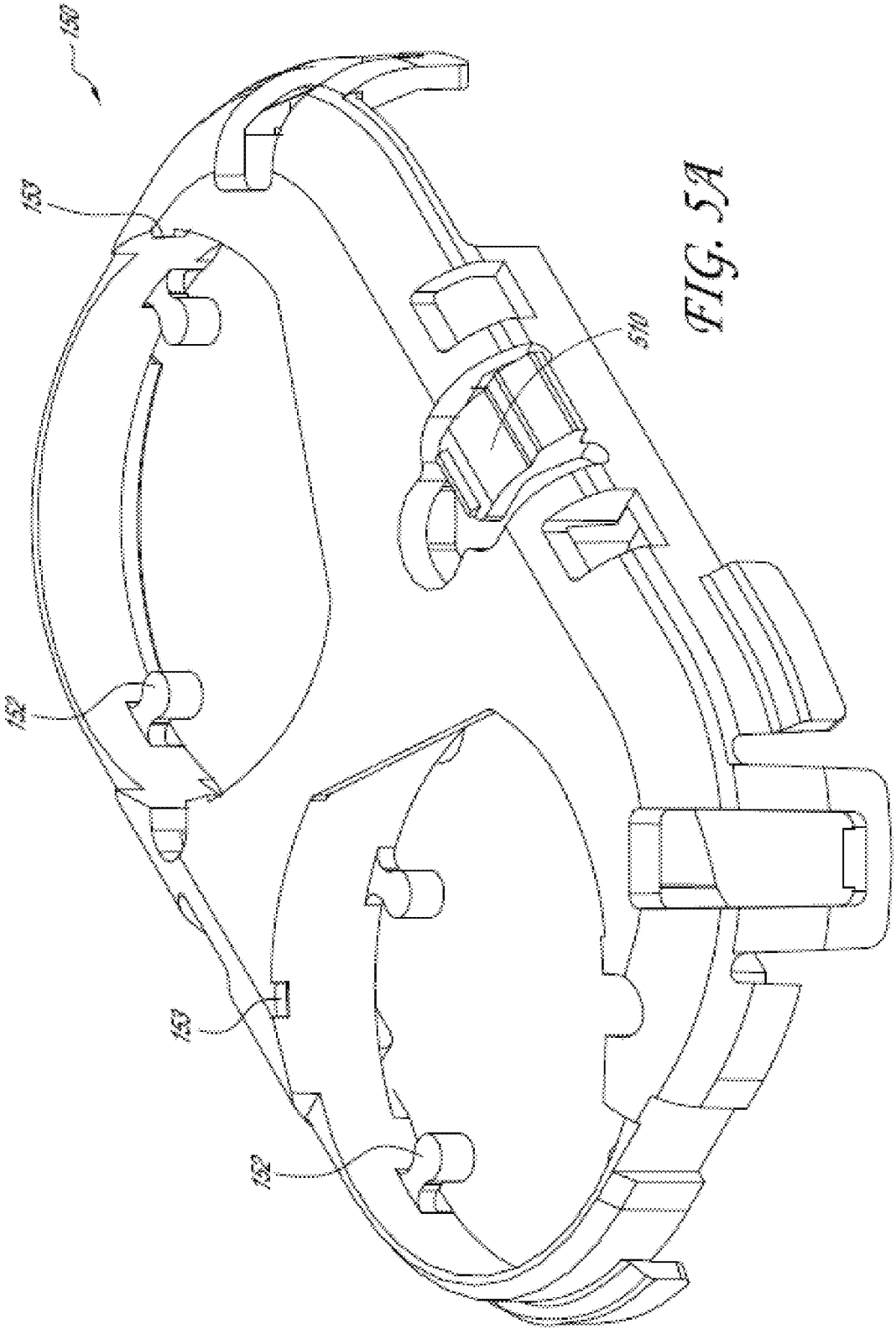


FIG. 4



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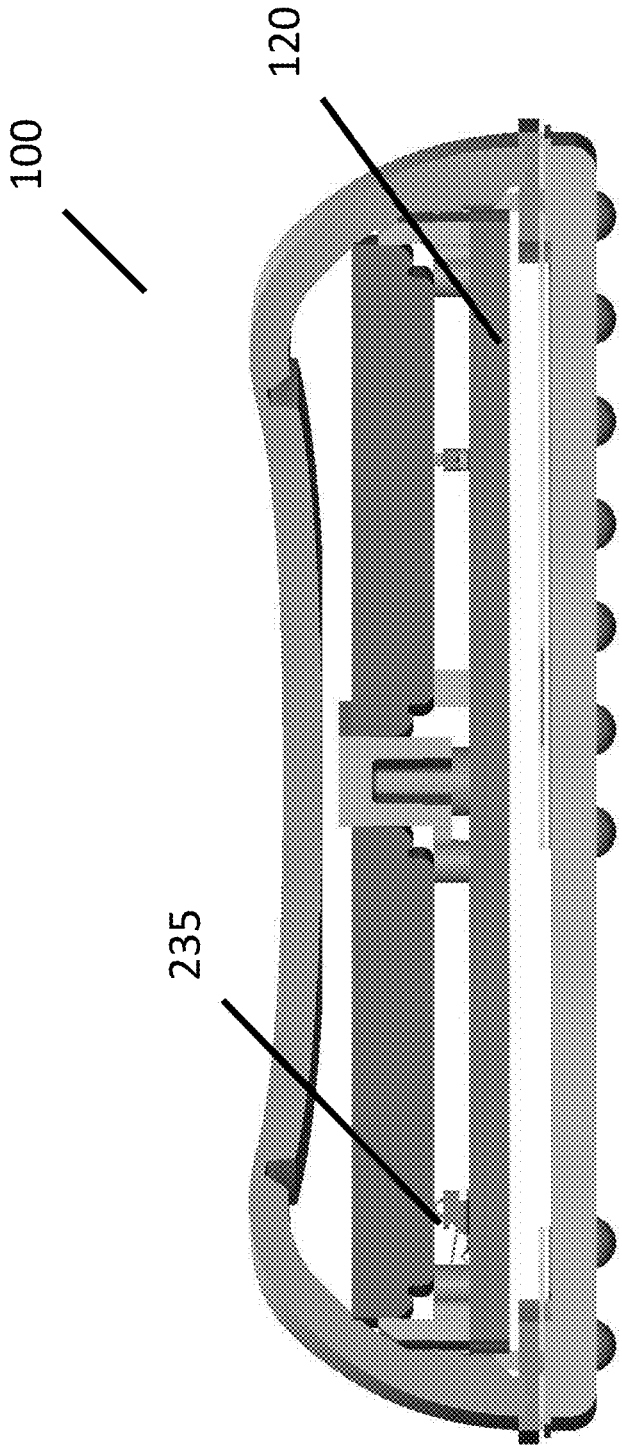


FIG. 5B

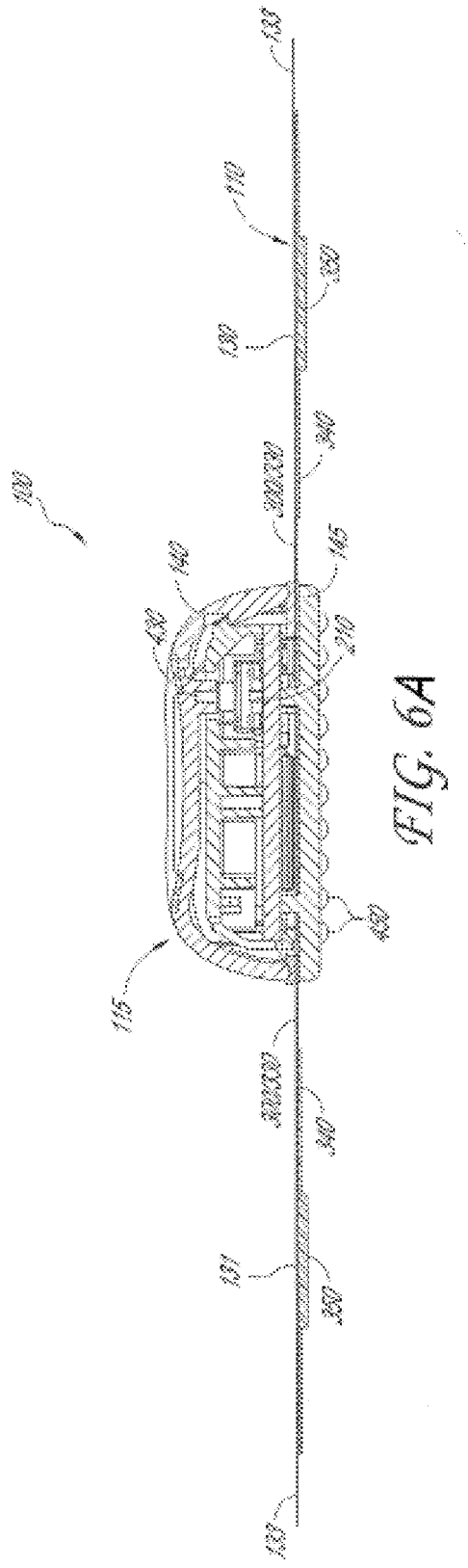
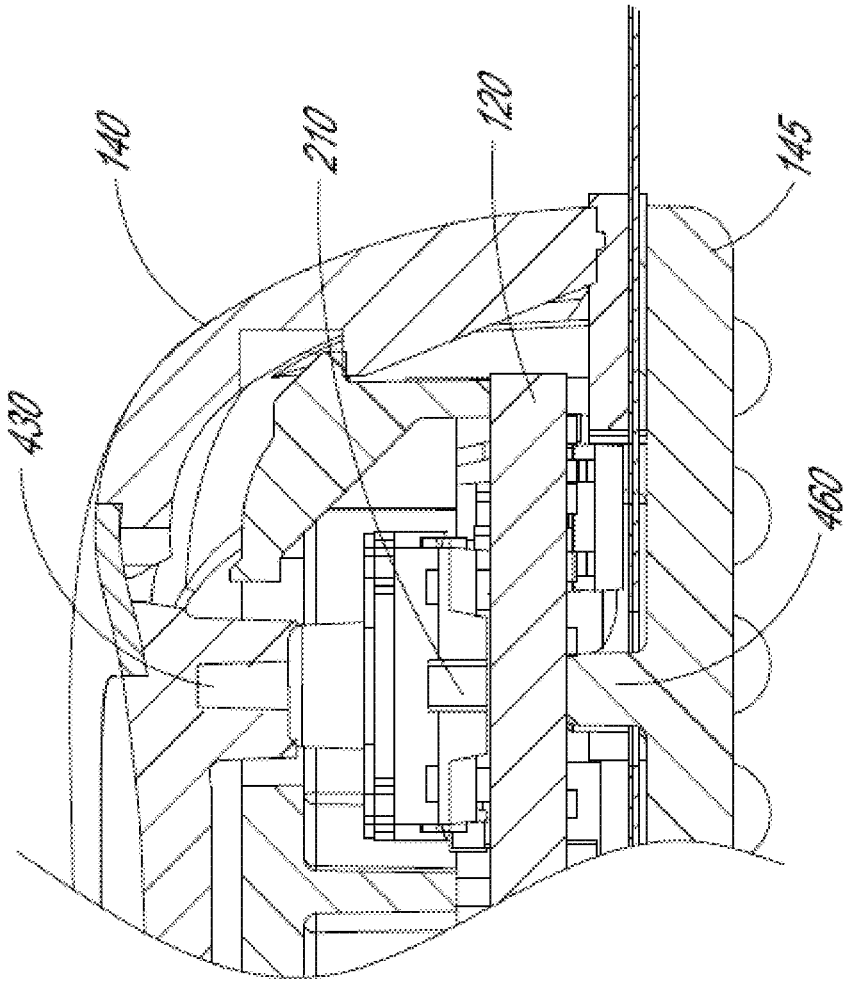


FIG. 6A



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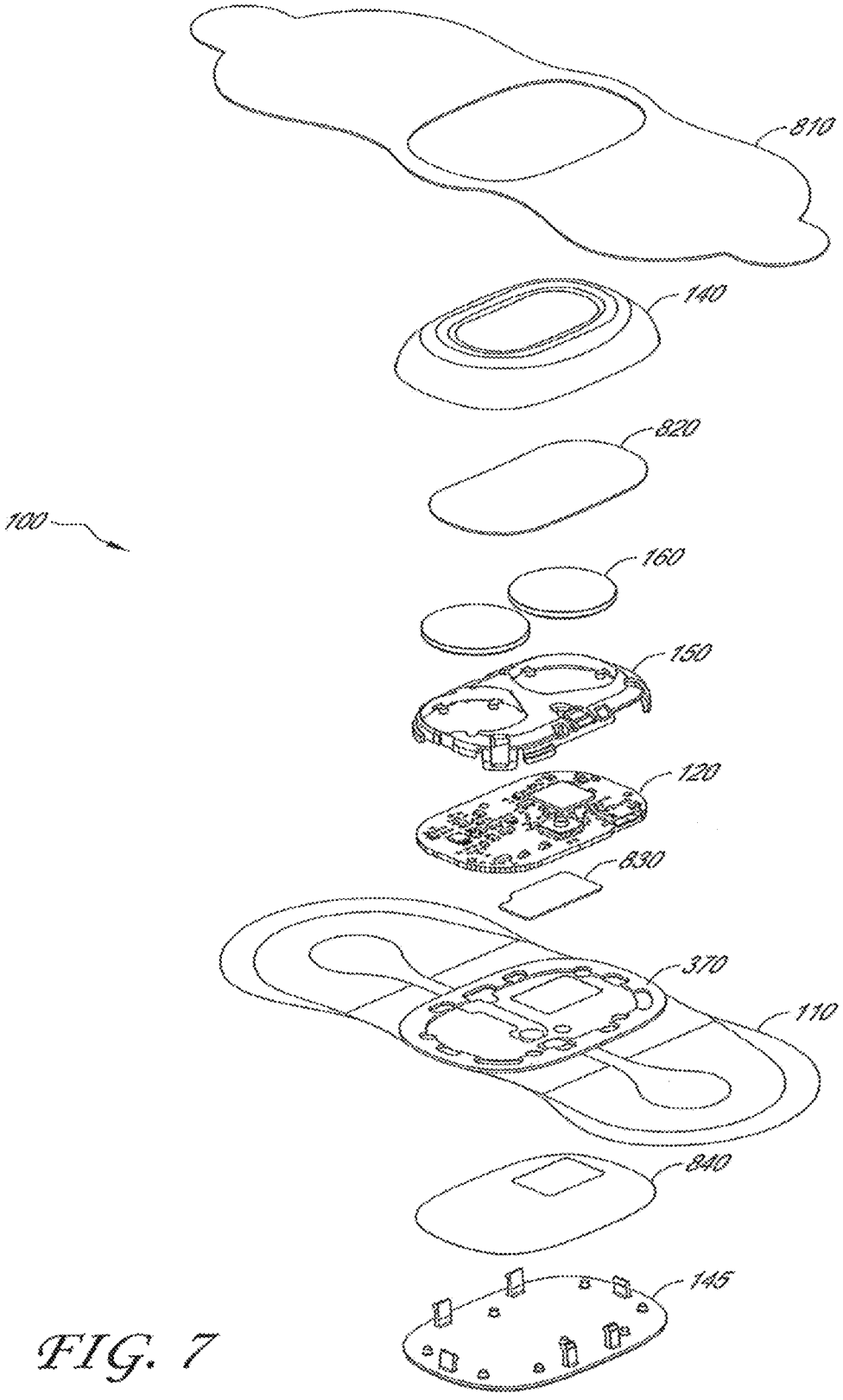

FIG. 7

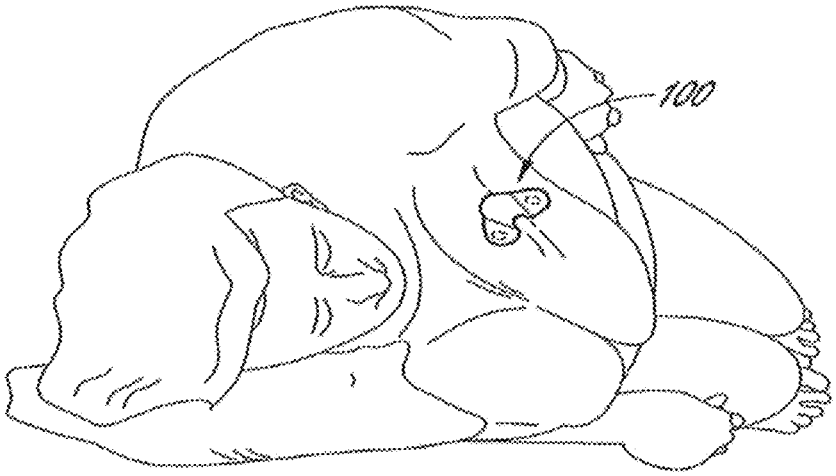

FIG. 8A

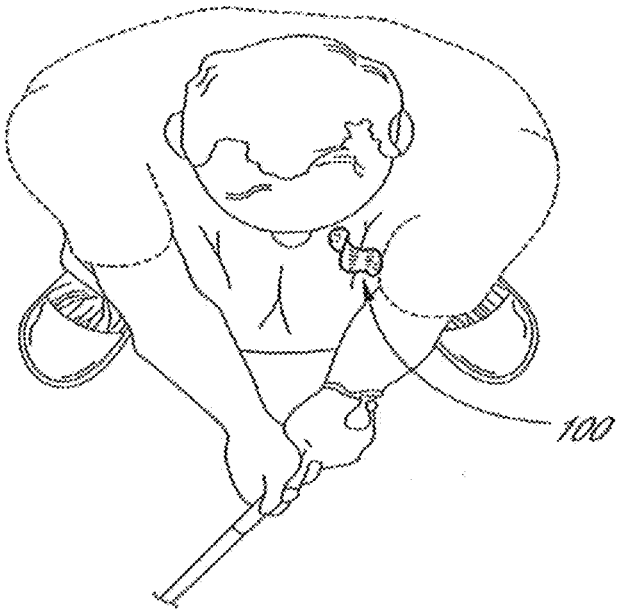

FIG. 8B

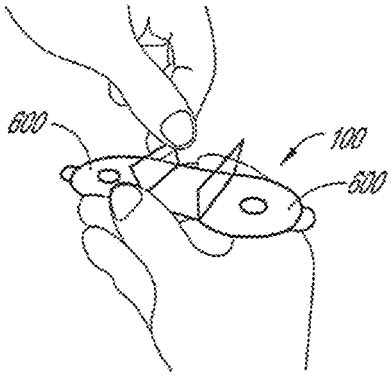

FIG. 9A

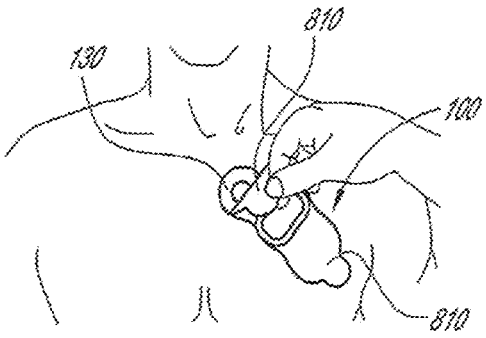

FIG. 9D

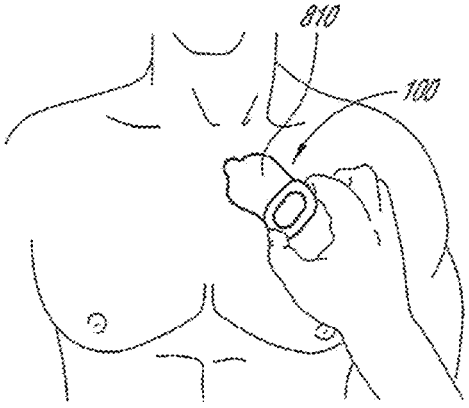

FIG. 9B

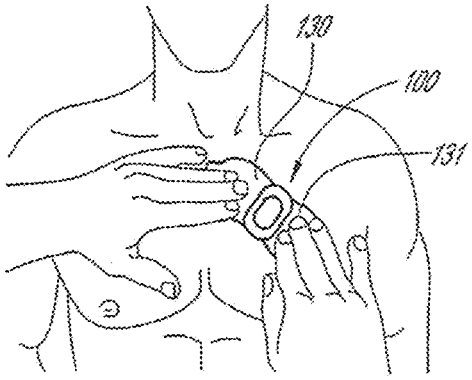

FIG. 9E

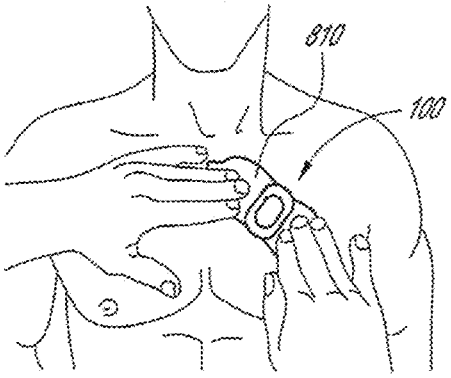

FIG. 9C

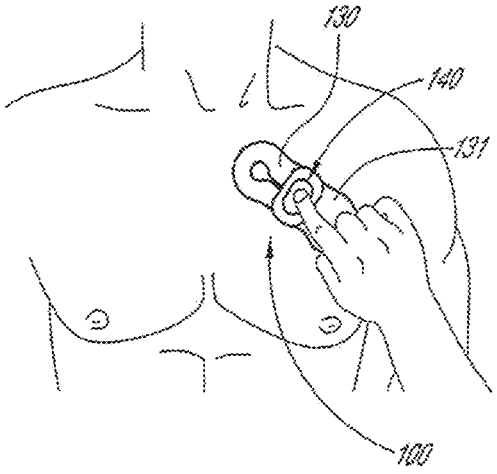

FIG. 9F

PHYSIOLOGICAL MONITORING DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 18/301,881, filed Apr. 17, 2023, which is a continuation of U.S. patent application Ser. No. 16/786,831, filed Feb. 10, 2020, which is a continuation of U.S. patent application Ser. No. 16/397,651, filed Apr. 29, 2019, which is a continuation of U.S. patent application Ser. No. 16/006,719, filed Jun. 12, 2018, which is a continuation of Ser. No. 14/162,656, filed, Jan. 23, 2014, which claims the benefit of U.S. Provisional Application No. 61/756,326, filed Jan. 24, 2013, entitled PHYSIOLOGICAL MONITORING DEVICE. The contents of the aforementioned applications are hereby incorporated by reference in their entireties as if fully set forth herein. The benefit of priority to the foregoing provisional application is claimed under the appropriate legal basis, including, without limitation, under 35 U.S.C. § 119 (e).

BACKGROUND

Field of the Invention

The invention relates generally to medical devices. More specifically, the invention relates to a physiological monitoring device and method for use.

Description of the Related Art

Abnormal heart rhythms, or arrhythmias, may cause various types of symptoms, such as loss of-consciousness, palpitations, dizziness, or even death. An arrhythmia that causes such symptoms is often an indicator of significant underlying heart disease. It is important to identify when such symptoms are due to an abnormal heart rhythm, since treatment with various procedures, such as pacemaker implantation or percutaneous catheter ablation, can successfully ameliorate these problems and prevent significant symptoms and death.

Since the symptoms listed above can often be due to other, less serious causes, a key challenge is to determine when any of these symptoms are due to an arrhythmia. Oftentimes, arrhythmias occur infrequently and/or episodically, making rapid and reliable diagnosis difficult. Currently, cardiac rhythm monitoring is primarily accomplished through the use of devices, such as Holter monitors, that use short-duration (<1 day) electrodes affixed to the chest. Wires connect the electrodes to a recording device, usually worn on a belt. The electrodes need daily changing and the wires are cumbersome. The devices also have limited memory and recording time. Wearing the device interferes with patient movement and often precludes performing certain activities while being monitored, such as bathing. All of these limitations severely hinder the diagnostic usefulness of the device, the compliance of patients using the device and the likelihood of capturing all important information. Lack of compliance and the shortcomings of the devices often lead to the need for additional devices, follow-on monitoring or other tests to make a correct diagnosis.

Current methods to correlate symptoms with the occurrence of arrhythmias, including the use of cardiac rhythm monitoring devices, such as Holter monitors and cardiac event recorders, are often not sufficient to allow an accurate diagnosis to be made. In fact, Holter monitors have been shown to not lead to a diagnosis up to 90% of the time ("Assessment of the Diagnostic Value of 24-Hour Ambulatory Electrocariographic Monitoring", by D E Ward et al. Biotelemetry Patient Monitoring, vol. 7, published in 1980).

Additionally, the medical treatment process to actually obtain a cardiac rhythm monitoring device and initiate monitoring is typically very complicated. There are usually numerous steps involved in ordering, tracking, monitoring, retrieving, and analyzing the data from such a monitoring device. In most cases, cardiac monitoring devices used today are ordered by a cardiologist or a cardiac electrophysiologist (EP), rather than the patient's primary care physician (PCP). This is of significance since the PCP is often the first physician to see the patient and determine that the patient's symptoms could be due to an arrhythmia. After the patient sees the PCP, the PCP will make an appointment for the patient to see a cardiologist or an EP. This appointment is usually several weeks from the initial visit with the PCP, which in itself leads to a delay in making a potential diagnosis as well as increases the likelihood that an arrhythmia episode will occur and go undiagnosed. When the patient finally sees the cardiologist or EP, a cardiac rhythm monitoring device will usually be ordered. The monitoring period can last 24-48 hours (Holter monitor) or up to a month (cardiac event monitor or mobile telemetry device). Once the monitoring has been completed, the patient typically must return the device to the clinic, which itself can be an inconvenience. After the data has been processed by the monitoring company or by a technician on-site at a hospital or office, a report will finally be sent to the cardiologist or EP for analysis. This complex process results in fewer patients receiving cardiac rhythm monitoring than would ideally receive it.

To address some of these issues with cardiac monitoring, the assignee of the present application developed various embodiments of a small, long-term, wearable, physiological monitoring device. One embodiment of the device is the Zio® Patch (www.irhythmtech.com). Various embodiments are also described, for example, in U.S. Pat. Nos. 8,150,502, 8,160,682 8,244,335, 8,560,046, and 8,538,503, the full disclosures of which are hereby incorporated by reference. Generally, the physiological monitors described in the above references fit comfortably on a patient's chest and are designed to be worn for at least one week and typically two to three weeks. The monitors detect and record cardiac rhythm signal data continuously while the device is worn, and this cardiac rhythm data is then available for processing and analysis.

These smaller, long-term physiological monitoring devices provided many advantages over prior art devices. At the same time, further improvements are desired. One of the most meaningful areas for improvement exists around increasing fidelity of the recorded ECG signal. This is particularly important for single-channel embodiments where a second vector of ECG is not available to clarify whether aberrances in signal are due to arrhythmia or signal artifact. Increases in signal to noise ratio as well as reduction of motion artifact improve efficiency in both algorithmic and human analysis of the recorded ECG signal.

Signal quality is important throughout the duration of wear, but it is particularly critical where the patient marks the record, indicating an area of symptomatic clinical significance. Marking the record is most easily enabled through a trigger located on the external surface of the device. However, since the trigger is part of a skin-contacting platform with integrated electrodes, the patient can introduce significant motion artifacts when feeling for the trigger.

A desirable device improvement would be a symptom trigger that can be activated with minimal addition of motion artifact.

Secondly, patient compliance and device adhesion performance are two factors that govern the duration of the ECG record and consequently the diagnostic yield. Compliance can be increased by improving the patient's wear experience, which is affected by wear comfort, device appearance and the extent to which the device impedes the normal activities of daily living. Given that longer ECG records provide greater diagnostic yield and hence value, improvements to device adhesion and patient compliance are desirable.

Finally, it is desirable for the device to be simple and cost effective to manufacture, enabling scalability at manufacturing as well as higher quality due to repeatability in process. Simplicity of manufacture can also lead to ease of disassembly, which enables the efficient recovery of the printed circuit board for quality-controlled reuse in another device. Efficient reuse of this expensive component is critical for decreasing the cost of the diagnostic monitor. At least some of the objectives will be met by the embodiments described below.

BRIEF SUMMARY

Embodiments described herein are directed to a physiological monitoring device that may be worn continuously and comfortably by a human or animal subject for at least one week or more and more typically two to three weeks or more. In one embodiment, the device is specifically designed to sense and record cardiac rhythm (i.e., electrocardiogram, ECG) data, although in various alternative embodiments one or more additional physiological parameters may be sensed and recorded. The physiological monitoring device includes a number of features to facilitate and/or enhance the patient experience, to make diagnosis of cardiac arrhythmias more accurate, and to make manufacture of the device more simple and cost effective.

In some embodiments, an electronic device for monitoring physiological signals in a mammal comprises:

- at least two flexible wings extending laterally from a rigid housing, wherein the flexible wings comprise a first set of materials which enable the wings to conform to a surface of the mammal and the rigid housing comprises a second set of materials;
- a printed circuit board assembly housed within the rigid housing, wherein the rigid housing is configured to prevent deformation of the printed circuit board in response to movement of the mammal;
- at least two electrodes embedded within the flexible wings, the electrodes configured to provide conformal contact with the surface of the mammal and to detect the physiological signals of the mammal;
- at least two electrode traces embedded within the wings and mechanically decoupled from the rigid housing, the electrode traces configured to provide conformal contact with the surface of the mammal and transmit electrical signals from the electrodes to the printed circuit board assembly; and,
- at least one hinge portion connecting the wings to the rigid housing, the hinge portions configured to flex freely at the area where it is joined to the rigid housing.

In certain embodiments, each wing may comprise an adhesive. In embodiments, the electrodes can be in the same plane as the adhesive. In certain embodiments, each wing comprises at least one rim, wherein the rim is thinner than an adjacent portion of each wing. The rigid housing may further comprise dimples configured to allow for airflow between the rigid housing and the surface of the mammal. In certain embodiments, the rim is configured to prevent the release of a portion of the wing from the surface of the mammal. In some embodiments, an electronic device for monitoring physiological systems may comprise a measuring instrument configured to detect motion signals in at least one axis. This measuring instrument may be an accelerometer that can be configured to detect motion signals in three axes.

In embodiments, the motion signals can be collected in time with the physiological signals. In certain embodiments, a motion artifact is identified when the physiological signals and the motion signals match. Further embodiments may call for an event trigger coupled to the printed circuit board assembly. In some embodiments, the event trigger input is supported by the rigid housing so as to prevent mechanical stress on the printed circuit board when the trigger is activated. The event trigger may be concave and larger than a human finger such that the event trigger is easily located. In certain embodiments, the electrode traces are configured to minimize signal distortion during movement of the mammal. In particular embodiments, gaskets may be used as a means for sealable attachment to the rigid housing.

In certain embodiments, a method for monitoring physiological signals in a mammal may comprise:

- attaching an electronic device to the mammal, wherein the device comprises:
- at least two electrodes configured to detect physiological signals from the mammal,
- at least one measuring instrument configured to detect secondary signals, and
- at least two electrode traces connected to the electrodes and a rigid housing; and,
- comparing the physiological signals to the secondary signals to identify an artifact.

In certain embodiments, identification of an artifact comprises a comparison between the frequency spectrum of the physiological signals and the frequency spectrum of the secondary signals. In embodiments, the secondary signals comprise motion signals that may be used to derive the activity and position of the mammal. In certain embodiments, the secondary signals are collected in three axes. In some embodiments, a tertiary signal may also be collected. In certain embodiments, the secondary signals comprise information about the connection between the electronic device and the mammal. In some embodiments, the secondary signals may be used to detect when the mammal is sleeping.

In some embodiments, a method of removing and replacing portions of a modular physiological monitoring device may comprise

- applying the device of claim **1** to a mammal for a period of time greater than 7 days and collecting physiological data;
- using the device of claim **1** to detect a first set of physiological signals;
- removing the device of claim **1** from the surface of the mammal;
- removing a first component from the device of claim **1**; and,
- incorporating the first component into a second physiological monitoring device, the second physiological monitoring device configured to detect a second set of physiological signals.

In some embodiments, the first component is electrically connected to other device components without the use of a permanent connection. In some embodiments, the device may further comprise spring connections. In certain embodiments, the first component may be preserved for a second use by a rigid housing to prevent damage. In particular embodiments, the first component is secured within a device by a mechanism that is capable of re-securing a second component once the first component is removed.

These and other aspects and embodiments of the invention are described in greater detail below, with reference to the drawing figures.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1**A and **1**B are perspective and exploded views, respectively, of a physiological monitoring device, according to one embodiment;

FIGS. **2**A and **2**B are top perspective and bottom perspective views, respectively, of a printed circuit board assembly of the physiological monitoring device;

FIGS. **3**A-E are perspective and exploded views of a flexible body and gasket of the physiological monitoring device;

FIG. **4** is an exploded view of a rigid housing of the physiological monitoring device;

FIG. **5**A-B is a perspective view of a battery holder of the physiological monitoring device;

FIGS. **6**A and **6**B are cross sectional views of the physiological monitoring device;

FIG. **7** is an exploded view of the physiological monitoring device including a number of optional items, according to one embodiment;

FIGS. **8**A and **8**B are perspective views of two people wearing the physiological monitoring device, illustrating how the device bends to conform to body movement and position; and

FIGS. **9**A-**9**F illustrate various steps for applying the physiological monitor to a patient's body, according to one embodiment.

DETAILED DESCRIPTION

The following description is directed to a number of various embodiments. The described embodiments, however, may be implemented and/or varied in many different ways without departing from the scope of the invention. For example, the described embodiments may be implemented in any suitable device, apparatus, or system to monitor any of a number of physiological parameters. For example, the following discussion focuses primarily on long-term, patch-based cardiac rhythm monitoring devices. In one alternative embodiment, a physiological monitoring device may be used, for example, for pulse oximetry and diagnosis of obstructive sleep apnea. In various alternative embodiments, one size of physiological monitor may be used for adult patients and another size may be used for pediatric patients. The method of using a physiological monitoring device may also vary. In some cases, a device may be worn for one week or less, while in other cases, a device may be worn for at least seven days and/or for more than seven days, for example between fourteen days and twenty-one days or even longer. Many other alternative embodiments and applications of the described technology are possible. Thus, the following description is provided for exemplary purposes only. Throughout the specification, reference may be made to the term "conformal." It will be understood by one of skill in the art that the term "conformal" as used herein refers to a relationship between surfaces or structures where a first surface or structure fully adapts to the contours of a second surface or structure.

Referring to FIGS. **1**A and **1**B, perspective and exploded views of one embodiment of a physiological monitoring device **100** are provided. As seen in FIG. **1**A, physiological monitoring device **100** may include a flexible body **110** coupled with a watertight, rigid housing **115**. Flexible body **110** (which may be referred to as "flexible substrate" or "flexible construct") typically includes two wings **130**, **131**, which extend laterally from rigid housing **115**, and two flexible electrode traces **311**, **312**, each of which is embedded in one of wings **130**, **131**. Each electrode trace **311**, **312** is coupled, on the bottom surface of flexible body **110**, with a flexible electrode (not visible in FIG. **1**A). The electrodes are configured to sense heart rhythm signals from a patient to which monitoring device **100** is attached. Electrode traces **311**, **312** then transmit those signals to electronics (not visible in FIG. **1**A) housed in rigid housing **115**. Rigid housing **115** also typically contains a power source, such as one or more batteries.

As will be explained in further detail below, the combination of a highly flexible body **110**, including flexible electrodes and electrode traces **311**, **312**, with a very rigid housing **115** may provide a number of advantages. For example, flexible body **110** includes a configuration and various features that facilitate comfortable wearing of device **100** by a patient for fourteen (**14**) days or more without removal. Rigid housing **115**, which typically does not adhere to the patient in the embodiments described herein, includes features that lend to the comfort of device **100**. Rigid housing **115** also protects the electronics and power source contained in housing **120**, enhances the ability of a patient to provide an input related to a perceived cardiac event, and allows for simple manufacturing and reusability of at least some of the contents of housing **115**. These and other features of physiological monitoring device **100** are described in greater detail below.

Referring now to FIG. **1**B, a partially exploded view of physiological monitoring device **100** illustrates component parts that make up, and that are contained within, rigid housing **115** in greater detail. In this embodiment, rigid housing **115** includes an upper housing member **140**, which detachably couples with a lower housing member **145**. Sandwiched between upper housing member **140** and lower housing member **145** are an upper gasket **370**, and a lower gasket **360** (not visible on FIG. **1**B but just below upper gasket **370**). Gaskets **370**, **360** help make rigid housing member **115** watertight when assembled. A number of components of monitoring device **100** may be housed between upper housing member **140** and lower housing member **145**. For example, in one embodiment, housing **115** may contain a portion of flexible body **110**, a printed circuit board assembly (PCBA) **120**, a battery holder **150**, and two batteries **160**. Printed circuit board assembly **120** is positioned within housing **115** to contact electrode traces **311**, **312** and batteries **160**. In various embodiments, one or more additional components may be contained within or attached to rigid housing **115**. Some of these optional components are described further below, in reference to additional drawing figures.

Battery holder **150**, according to various alternative embodiments, may hold two batteries (as in the illustrated embodiment), one battery, or more than two batteries. In other alternative embodiments, other power sources may be used. In the embodiment shown, battery holder **150** includes

multiple retain tabs **153** for holding batteries **160** in holder **150**. Additionally, battery holder **150** includes multiple feet **152** to establish correct spacing of batteries **160** from the surface of PCBA **120** and ensure proper contact with spring fingers **235** and **236**. Spring fingers **235** and **236** are used in this embodiment rather than soldering batteries **160** to PCBA **120**. Although soldering may be used in alternative embodiments, one advantage of spring fingers **235** and **236** is that they allow batteries **160** to be removed from PCBA **120** and holder **150** without damaging either of those components, thus allowing for multiple reuses of both. Eliminating solder connections also simplifies and speeds up assembly and disassembly of monitoring device **100**.

In some embodiments, upper housing member **140** may act as a patient event trigger. When a patient is wearing physiological monitoring device **100** for cardiac rhythm monitoring, it is typically advantageous for the patient to be able to register with device **100** (i.e., log into the device's memory) any cardiac events perceived by the patient. If the patient feels what he/she believes to be an episode of heart arrhythmia, for example, the patient may somehow trigger device **100** and thus provide a record of the perceived event. At some later time, the patient's recorded perceived event could be compared with the patient's actual heart rhythm, recorded by device **100**, and this may help determine whether the patient's perceived events correlate with actual cardiac events. One problem with patient event triggers in currently available wearable cardiac rhythm monitoring devices, however, is that a small trigger may be hard to find and/or activate, especially since the monitoring device is typically worn under clothing. Additionally, pressing a trigger button may affect the electronics and/or the electrodes on the device in such a way that the recorded heart rhythm signal at that moment is altered simply by the motion caused to the device by the patient triggering. For example, pressing a trigger may jar one or both of the electrodes in such a way that the recorded heart rhythm signal at that moment appears like an arrhythmia, even if no actual arrhythmia event occurred. Additionally, there is a chance that the trigger may be inadvertently activated, for instance while sleeping or laying on the monitoring device.

In the embodiment shown in FIGS. **1**A and **1**B, however, rigid housing **115** is sufficiently rigid, and flexible body **110** is sufficiently flexible, that motion applied to housing **115** by a patient may rarely or ever cause an aberrant signal to be sensed by the electrodes. In this embodiment, the central portion of upper housing member **140** is slightly concave and, when pressed by a patient who is wearing device **100**, this central portion depresses slightly to trigger a trigger input on PCBA **120**. Because the entire upper surface of rigid housing **115** acts as the patient event trigger, combined with the fact that it is slightly concave, it will generally be quite easy for a patient to find and push down the trigger, even under clothing. Additionally, the concave nature of the button allows it to be recessed which protects it from inadvertent activations. Thus, the present embodiment may alleviate some of the problems encountered with patient event triggers on currently available heart rhythm monitors. These and other aspects of the features shown in FIGS. **1**A and **1**B will be described in further detail below.

Referring now to FIGS. **2**A and **2**B, printed circuit board assembly **120** (or "PCBA") may include a top surface **220**, a bottom surface **230**, a patient trigger input **210** and spring contacts **235**, **236**, and **237**. Printed circuit board assembly **120** may be used to mechanically support and electrically connect electronic components using conductive pathways, tracks or electrode traces **311**, **312**. Furthermore, because of the sensitive nature of PCBA **120** and the requirement to mechanically interface with rigid body **115**, it is beneficial to have PCBA **120** be substantially rigid enough to prevent unwanted deflections which may introduce noise or artifact into the ECG signal. This is especially possible during patient trigger activations when a force is transmitted through rigid body **115** and into PCBA **120**. One way to ensure rigidity of the PCBA is to ensure that the thickness of the PCBA is relatively above a certain value. For example, a thickness of at least about 0.08 cm is desirable and, more preferably, a thickness of at least about 0.17 cm is desirable. In this application, PCBA **120** may also be referred to as, or substituted with, a printed circuit board (PCB), printed wiring board (PWB), etched wiring board, or printed circuit assembly (PCA). In some embodiments, a wire wrap or point-to-point construction may be used in addition to, or in place of, PCBA **120**. PCBA **120** may include analog circuits and digital circuits.

Patient trigger input **210** may be configured to relay a signal from a patient trigger, such as upper housing member **140** described above, to PCBA **120**. For example, patient trigger input **210** may be a PCB switch or button that is responsive to pressure from the patient trigger (i.e., the upper surface of upper housing portion **140**). In various embodiments, patient trigger input **210** may be a surface mounted switch, a tactile switch, an LED illuminated tactile switch, or the like. In some embodiments, patient trigger input **210** may also activate an indicator, such as an LED.

One important challenge in collecting heart rhythm signals from a human or animal subject with a small, two-electrode physiological monitoring device such as device **100** described herein, is that having only two electrodes can sometimes provide a limited perspective when trying to discriminate between artifact and clinically significant signals. For example, when a left-handed patient brushes her teeth while wearing a small, two-electrode physiological monitoring device on her left chest, the tooth brushing may often introduce motion artifact that causes a recorded signal to appear very similar to Ventricular Tachycardia, a serious heart arrhythmia. Adding additional leads (and, hence, vectors) is the traditional approach toward mitigating this concern, but this is typically done by adding extra wires adhered to the patient's chest in various locations, such as with a Holter monitor. This approach is not consistent with a small, wearable, long term monitor such as physiological monitoring device **100**.

An alternate approach to the problem described above is to provide one or more additional data channels to aid signal discrimination. In some embodiments, for example, device **100** may include a data channel for detecting patch motion. In certain embodiments, an accelerometer may provide patch motion by simply analyzing the change in magnitude of a single axis measurement, or alternatively of the combination of all three axes. The accelerometer may record device motion at a sufficient sampling rate to allow algorithmic comparison of its frequency spectrum with that of the recorded ECG signal. If there is a match between the motion and recorded signal, it is clear that the device recording in that time period is not from a clinical (e.g., cardiac) source, and thus that portion of the signal can be confidently marked as artifact. This technique may be particularly useful in the tooth brushing motion example aforementioned, where the rapid frequency of motion as well as the high amplitude artifact is similar to the heart rate and morphology, respectively, of a potentially life-threatening arrhythmia like Ventricular Tachycardia.

In some embodiments, using the magnitude of all three axes for such an analysis would smooth out any sudden changes in values due to a shift in position rather than a change in activity. In other embodiments, there may be some advantage in using a specific axis of measurement such as along the longitudinal axis of the body to focus on a specific type of artifact introduced by upward and downward movements associated with walking or running. In a similar vein, the use of a gyroscope in conjunction with the accelerometer may provide further resolution as to the nature of the motion experienced. While whole body movements may be sufficiently analyzed with an accelerometer on its own, specific motion of interest such as rotational motion due to arm movement is sufficiently complex that an accelerometer alone might not be able to distinguish.

In addition to detecting motion artifact, an accelerometer tuned to the dynamic range of human physical activities may provide activity levels of the patient during the recording, which can also enhance accuracy of algorithmic true arrhythmia detection. Given the single-lead limitation of device **100**, arrhythmias that require observation of less prominent waves (e.g. P-wave) in addition to rate changes such as Supraventricular Tachycardia pose challenges to both computerized algorithms as well as the trained human eye. This particular arrhythmia is also characterized by the sudden nature of its onset, which may be more confidently discriminated from a non-pathological Sinus Tachycardia if a sudden surge in the patient's activity level is detected at the same time as the increase in heart rate. Broadly speaking, the provision of activity information to clinical professionals may help them discriminate between exercise-induced arrhythmia versus not. As with motion artifact detection, a single-axis accelerometer measurement optimized to a particular orientation may aid in more specifically determining the activity type such as walking or running. This additional information may help explain symptoms more specifically and thereby affect the subsequent course of therapeutic action.

In certain embodiments, an accelerometer with 3 axes may confer advantages beyond what magnitude of motions can provide. When the subject is not rapidly moving, 3-dimensional accelerometer readings may approximate the tilt of PCBA **120**, and therefore body orientation relative to its original orientation. The original body orientation can be assumed to be in either an upright or supine position which is required for appropriate positioning and application of the device to the body. This information may aid in ruling out certain cardiac conditions that manifest as beat-to-beat morphology changes, such as cardiac alternans where periodic amplitude changes are observed, often in heart failure cases. Similar beat-to-beat morphology changes are observable in healthy subjects upon shift in body position due to the shift in heart position relative to the electrode vector, for example from an upright to a slouching position. By design, the single-channel device **100** does not have an alternate ECG channel to easily rule out potential pathological shifts in morphology, however, correlation with shifts in body orientation will help explain these normal changes and avoid unnecessary treatment due to false diagnosis.

In other embodiments, the accelerometer may also be used as a sleep indicator, based on body orientation and movement. When presenting clinical events (e.g., pauses), it is diagnostically helpful to be able to present information in a manner that clearly separates events that occurred during sleep from those during waking hours. In fact, certain algorithms such as for ECG-derived respiratory rate only make sense to run when the patient is in a relatively motionless state and therefore subtle signal modulation introduced by chest movement due to breathing is observable. Respiratory rate information is useful as one channel of information necessary to detect sleep apnea in certain patient populations.

In certain embodiments, the accelerometer may also be used to detect free-falls, such as fainting. With an accelerometer, device **100** may be able to mark fainting (syncope) and other free-fall events without relying on patient trigger. In order to allow timely detection of such critical events, yet considering the battery and memory limitations of a small, wearable device such as device **100**, acquisition of accelerometer readings may be done in bursts, where only interesting information such as a potential free fall is written to memory at a high sampling rate. An expansion of this event-trigger concept is to use specific tapping motions on device **100** as a patient trigger instead of or in conjunction with the button previously described. The use and detection of multiple types of tapping sequences may provide better resolution and accuracy into what exactly the patient was feeling, instead of relying on the patient to manually record their symptom and duration in a trigger log after the fact. An example of such added resolution is to indicate the severity of the symptom by the number of sequential taps.

Alternatively, in other embodiments, an optical sensors may be used to distinguish between device motion and patient body motion. Further, in additional embodiments, the device may not require a button or trigger.

Another optional data channel that may be added to physiological monitoring device **100** is a channel for detecting flex and/or bend of device **100**. In various embodiments, for example, device **100** may include a strain gauge, piezoelectric sensor or optical sensor to detect motion artifact in device **100** itself and thus help to distinguish between motion artifact and cardiac rhythm data. Yet another optional data channel for device **100** may be a channel for detecting heart rate. For example, a pulse oximeter, microphone or stethoscope may provide heart rate information. Redundant heart rate data may facilitate discrimination of ECG signals from artifact. This is particularly useful in cases where arrhythmia such as Supraventricular Tachycardia is interrupted by artifact, and decisions must be made whether the episode was actually multiple shorter episodes or one sustained episode. Another data channel may be included for detecting ambient electrical noise. For example, device **100** may include an antenna for picking up electromagnetic interference. Detection of electromagnetic interference may facilitate discrimination of electrical noise from real ECG signals. Any of the above-described data channels may be stored to support future noise discrimination or applied for immediate determination of clinical validity in real-time.

With reference now to FIGS. **3**A and **3**B, flexible body **110** is shown in greater detail. As illustrated in FIG. **3**A, flexible body **110** may include wings **130**, **131**, a thin border **133** (or "rim" or "edge") around at least part of each wing **130**, **131**, electrode traces **311**, **312**, and a hinge portion **132** (or "shoulder") at or near a junction of each wing **130**, **131** with rigid housing **115**. Also shown in FIG. **3**A is upper gasket **370**, which is not considered part of flexible body **110** for this description, but which facilitates attachment of flexible body **110** to rigid housing **115**.

Hinge portions **132** are relatively thin, even more flexible portions of flexible body **110**. They allow flexible body **110** to flex freely at the area where it is joined to rigid housing **115**. This enhances comfort, since when the patient moves, housing **115** can freely lift off of the patient's skin. Electrode traces **311**, **312** are also very thin and flexible, to allow for

patient movement without signal distortion. Borders **133** are portions of flexible body **110** that is thinner than immediately adjacent portions and that provide for a smooth transition from flexible body **110** to a patient's skin, thus preventing edge-lift and penetration of dirt or debris below flexible body **110**.

As shown in greater detail in FIG. **3**B, flexible body **110** may include multiple layers. As mentioned previously, upper gasket **370** and lower gasket **360** are not considered part of flexible body **110** for the purposes of this description but are shown for completeness of description. This distinction is for case of description only, however, and should not be interpreted to limit the scope of the claimed invention. Flexible body **110** may include a top substrate layer **300**, a bottom substrate layer **330**, an adhesive layer **340**, and flexible electrodes **350**. Top and bottom substrate layers **300**, **330** may be made of any suitable, flexible material, such as one or more flexible polymers. Suitable flexible polymers can include, but are not limited to, polyurethane, polyethylene, polyester, polypropylene, nylon, teflon and carbon impregnated vinyl. The material of substrate layers **300**, **330** may be selected based on desired characteristics. For example, the material of substrate layers **300**, **330** may be selected for flexibility, resilience, durability, breathability, moisture transpiration, adhesion and/or the like. In one embodiment, for example, top substrate layer **300** may be made of polyurethane, and bottom substrate layer **330** may be made of polyethylene or alternatively polyester. In other embodiments, substrate layers **300**, **330** may be made of the same material. In yet another embodiment, substrate layer **330** may contain a plurality of perforations in the area over adhesive layer **340** to provide for even more breathability and moisture transpiration. In various embodiments, physiological monitoring device **100** may be worn continuously by a patient for as many as 14-21 days or more, without removal during the time of wear and with device **100** being worn during showering, exercising and the like. Thus, the material(s) used and the thickness and configuration of substrate layers **300**, **330** may be essential to the function of physiological monitoring device **100**. In some embodiments, the material of substrate layers **300**, **330** acts as an electric static discharge (ESD) barrier to prevent arcing.

Typically, top and bottom substrate layers **300**, **330** are attached to one another via adhesive placed on one or both layers **300**, **330**. For example, the adhesive or bonding substance between substrate layers **300**, **330** may be an acrylic-based, rubber-based, or silicone-based adhesive. In other alternative embodiments, flexible body **110** may include more than two layers of flexible material.

In addition to the choice of material(s), the dimensions—thickness, length and width—of substrate layers **300**, **330** may be selected based on desired characteristics of flexible body **110**. For example, in various embodiments, the thickness of substrate layers **300**, **330** may be selected to give flexible body **110** an overall thickness of between about 0.1 mm to about 1.0 mm. According to various embodiments, flexible body **110** may also have a length of between about 7 cm and 15 cm and a width of about 3 cm and about 6 cm. Generally, flexible body **110** will have a length sufficient to provide a necessary amount of separation between electrodes **350**. For example, a distance from the center of one electrode **350** to the center of the other electrode **350** should be at least about 6.0 cm and more preferably at least about 8.5 cm. This separation distance may vary, depending on the application. In some embodiments, substrate layers **300**, **330** may all have the same thickness. Alternatively, the two substrate layers **300**, **330** may have different thicknesses.

As mentioned above, hinge portions **132** allow the rigid body **115** to lift away from the patient while flexible body **110** remains adhered to the skin. The functionality of hinge portions **132** is critical in allowing the device to remain adhered to the patient throughout various activities that may stretch and compress the skin. Furthermore, hinge portions **132** allow for significantly improved comfort while wearing the device. Generally, hinge portions **132** will be sufficiently wide enough to provide adequate lift of rigid body **115** without creating too large of a peel force on flexible body **110**. For example, in various embodiments, the width of hinge portion **132** should be at least about 0.25 cm and more preferably at least about 0.75 cm.

Additionally, the shape or footprint of flexible body **110** may be selected based on desired characteristics. As seen in FIG. **3**A, wings **130**, **131** and borders **133** may have rounded edges that give flexible body **110** an overall "peanut" shape. However, wings **130**, **131** can be formed in any number of different shapes such as rectangles, ovals, loops, or strips. In the embodiment shown in FIGS. **3**A and **3**B, the footprint top substrate layer **300** is larger than the footprint of bottom substrate layer **330**, with the extension of top substrate layer **300** forming borders **133**. Thus, borders **133** are made of the same polyurethane material that top layer **300** is made of. Borders **133** are thinner than an adjacent portion of each wing **130**, **131**, since they includes only top layer **300**. The thinner, highly compliant rim **133** will likely enhance adherence of physiologic monitoring device **100** to a patient, as it provides a transition from an adjacent, slightly thicker portion of wings **130**, **131** to the patient's skin and thus helps prevent the edge of device **110** from peeling up off the skin. Border **133** may also help prevent the collection of dirt and other debris under flexible body **110**, which may help promote adherence to the skin and also enhance the aesthetics of device **110**. In alternative embodiments, the footprint of substrate layers **300**, **330** may be the same, thus eliminating borders **133**.

While the illustrated embodiments of FIGS. **1**A-**3**B include only two wings **130**, **131**, which extend from rigid housing **115** in approximately opposite directions (i.e., at a 180-degree angle relative to each other), other configurations are possible in alternative embodiments. For example, in some embodiments, wings **130**, **131** may be arranged in an asymmetrical orientation relative to one another and/or one or more additional wings may be included. As long as sufficient electrode spacing is provided to permit physiological signal monitoring, and as long as wings **130**, **131** are configured to provide extended attachment to the skin, any suitable configuration and number of wings **130**, **131** and electrode traces **311**, **312** may be used. The embodiments described above have proven to be advantageous for adherence, patient comfort and accuracy of collected heart rhythm data, but in alternative embodiments it may be possible to implement alternative configurations.

Adhesive layer **340** is an adhesive that is applied to two portions of the bottom surface of bottom substrate layer **330**, each portion corresponding to one of wings **130**, **131**. Adhesive layer **340** thus does not extend along the portion of bottom substrate layer **330** upon which rigid housing **115** is mounted. Adhesive layer **340** may be made of any suitable adhesive, although certain adhesives have been found to be advantageous for providing long term adhesion to patient skin with relative comfort and lack of skin irritation. For example, in one embodiment, adhesive layer **340** is a hydrocolloid adhesive. In another embodiment, the adhesive layer **340** is comprised of a hydrocolloid adhesive that

contains naturally-derived or synthetic absorbent materials which take up moisture from the skin during perspiration.

Each of the two portions of adhesive layer **340** includes a hole, into which one of electrodes **350** fits. Electrodes **350** made of flexible material to further provide for overall conformability of flexible body **110**. In one embodiment, for example, flexible electrodes **350** may be made of a hydrogel **350**. Electrodes **350** generally provide conformal, non-irritating contact with the skin to provide enhanced electrical connection with the skin and reduce motion artifact. In some embodiments, hydrogel electrodes **350** may be punched into adhesive layer **340**, thus forming the holes and filling them with hydrogel electrodes **350**. In one alternative embodiment, electrodes **350** and adhesive **340** may be replaced with an adhesive layer made of a conductive material, such that the entire adhesive layer on the underside of each wing **130**, **131** acts as an electrode. Such an adhesive layer may include a hybrid adhesive/conductive substance or adhesive substance mixed with conductive elements or particles. For example, in one embodiment, such an adhesive layer may be a hybrid of a hydrogel and a hydrocolloid adhesive.

As discussed above, in some embodiments, adhesive layer **340** may cover a portion of the underside of lower substrate layer **330**, such that at least a portion of the bottom side of flexible body **110** does not include adhesive layer **340**. As seen in FIG. **3**A, hinges **132** may be formed in the flexible body **110** as portions of each wing **130**, **131** on which adhesive layer **340** is not applied. Hinge portions **132** are generally located at or near the junction of flexible body **110** with rigid housing **115**, and thus provide for flexing of device **100** to accommodate patient movement. In some embodiments, hinge portions **132** may have a width that is less than that of adjacent portions of wings **130**, **131**, thus giving device **100** its "peanut" shape mentioned above. As shown in FIG. **8**, as a subject moves, device **100** flexes along with patient movement. Device flexion may be severe and is likely to occur many times during long term monitoring. Hinge portions **132** may allow for dynamic conformability to the subject, while the rigidity of rigid housing **115** may allow housing **115** to pop up off the patient's skin during device flexion, thus preventing peeling of the device **100** off of the skin at its edge.

Flexible body **110** further includes two electrode traces **311**, **312** sandwiched between upper substrate layer **300** and lower substrate layer **330**. Each electrode trace **311**, **312** may include an electrode interface portion **310** and an electrocardiogram circuit interface portion **313**. As illustrated in FIGS. **3**C and **3**D, ECG circuit interface portions **313** are in physical contact with spring fingers **237** and provide electrical communication with PCBA **120** when device **100** or zoomed-in device portion **101** is assembled. Electrode interface portions **310** contact hydrogel electrodes **350**. Thus, electrode traces **311**, **312** transmit cardiac rhythm signals (and/or other physiological data in various embodiments) from electrodes **350** to PCBA **120**.

The material and thickness of electrode traces **311**, **312** are important for providing a desired combination of flexibility, durability and signal transmission. For example, in one embodiment, electrode traces **311**, **312** may include a combination of silver (Ag) and silver chloride (AgCl). The silver and silver chloride may be disposed in layers. For example, one embodiment of electrode traces **311**, **312** may include a top layer of silver, a middle layer of carbon impregnated vinyl, and a bottom (patient-facing) layer of silver chloride. In another embodiment, both top and bottom layers of electrode traces **311**, **312** may be made of silver chloride. In one embodiment, the top and bottom layers may be applied to the middle layer in the form of silver ink and silver chloride ink, respectively. In an alternative embodiment, each electrode trace may include only two layers, such as a top layer of silver and a bottom layer of silver chloride. In various embodiments, the material of a bottom layer of each electrode trace **311**, **312**, such as AgCl, may be selected to match the chemistry of the hydrogel electrodes **350** and create a half-cell with the body of the subject.

The thickness of the electrode traces **311**, **312** may be selected to optimize any of a number of desirable properties. For example, in some embodiments, at least one of the layers of electrode traces **311**, **312** can be of a sufficient thickness to minimize or slow depletion of the material from an anode/cathode effect over time. Additionally, the thickness may be selected for a desired flexibility, durability and/or signal transmission quality. Flexible electrode traces **311**, **312** generally may help provide conformal contact with the subject's skin and may help prevent electrodes **350** from peeling or lifting off of the skin, thereby providing strong motion artifact rejection and better signal quality by minimizing transfer of stress to electrodes **350**.

As mentioned above, in some embodiments, top gasket **370** and bottom gasket **360** may be attached upper substrate **300** and lower substrate **330** of flexible body **110**. Gaskets **360**, **370** may be made of any suitable material, such as urethane, which provides a water tight seal between the upper housing member **140** and lower housing member **145** of rigid housing **115**. In one embodiment, top gasket **370** and/or bottom gasket **360** may include an adhesive surface. FIG. **3**E depicts yet another embodiment where top gasket **370** includes tabs **371** that protrude away from the profile of top housing **140** while still being adhered to upper substrate **300**. The tabs **371** cover a portion of electrode traces **311**, **312** and provide a strain relief for the traces at the point of highest stress where the flexible body meets the rigid housing.

With reference now to FIG. **4**, upper housing member **140** and lower housing member **145** of rigid housing **115** are shown in greater detail. Upper and lower housing members **140**, **145** may be configured, when coupled together with gaskets **360**, **370** in between, to form a watertight enclosure for containing PCBA **120**, battery holder **150**, batteries **160** and any other components contained within rigid housing **115**. Housing members **140**, **145** may be made of any suitable material to protect internal components, such as water resistant plastic. In one embodiment, upper housing member **140** may include a rigid sidewall **440**, a light pipe **410** to transmit visual information from the LEDs on the PCBA through the housing member, a slightly flexible top surface **420**, and an inner trigger member **430** extending inward from top surface **420**. Top surface **420** is configured to be depressed by a patient when the patient perceives what he or she believes to be an arrhythmia or other cardiac event. When depressed, top surface **420** depresses inner trigger member **430**, which contacts and activates trigger input **210** of PCBA **120**. Additionally, as discussed previously, top surface **420** may have a concave shape (concavity facing the inside of housing **115**) to accommodate the shape of a finger. It is believed that the design of upper housing member **140** isolates activation of the trigger input **210** from electrodes **350**, thereby minimizing artifact in the data recording.

With continued reference to FIG. **4**, lower housing member **145** may be configured to detachably connect with upper housing member **140** in such a way that housing members **140**, **145** may be easily attached and detached for reusability of at least some of the component parts of monitoring device **100**. In some embodiments, a bottom surface **445** (patient

facing surface) of lower housing member **145** may include multiple dimples **450** (or "bumps," "protrusions" or the like), which will contact the patient's skin during use. Dimples **450** may allow for air flow between bottom surface **445** and the patient's skin, thus preventing a seal from forming between bottom surface **445** and the skin. It is believed that dimples **450** improve comfort and help prevent a perception in currently available devices in which the patient feels as if monitoring device **100** is falling off when it housing **115** lifts off the skin and breaks a seal with the skin. In yet another embodiment the bottom surface **445** of lower housing member **450** may include multiple divots (recesses instead of protrusions) to prevent a seal from forming.

Referring now to FIG. **5**A, battery holder **150** is shown in greater detail. Battery holder **150** may be made of plastic or other suitable material, is configured to be mounted to PCBA **120** and subsequently attached to rigid housing **115**, and is capable of holding two batteries **160** (FIG. **1**B). In alternative embodiments, battery holder **150** may be configured to hold one battery or more than two batteries. A plurality of protrusions **152** provide a stable platform for batteries **160** to be positioned a fixed distance above the surface of PCBA **120**, avoiding unwanted contact with sensitive electronic components yet providing for adequate compression of spring contacts **235** (FIG. **5**B). Protrusions **153** lock batteries **160** into position and resist the upward force on the batteries from spring contacts **235**. Battery holder **150** also positions batteries appropriately **160** to provide for adequate compression of spring contacts **236**. Use of battery holder **150** in conjunction with spring contacts **235** and **236** allows for batteries **160** to be electrically connected to PCBA **120** while still having additional electronic components between batteries **160** and PCBA **120** and maintain a very compact assembly. Battery holder **150** may include a flexible hook **510** which engages a corresponding rigid hook **440** of upper housing member **140**. Under normal assembly conditions the flexible hook **510** remains securely mated with rigid hook **440**. For disassembly, flexible hook **510** can be pushed and bent using an appropriate tool passed through top housing **140** causing it to disengage from rigid hook **440** and subsequently allow top housing **140** to be removed.

With reference now to FIGS. **6**A and **6**B, physiological monitoring device **100** is shown in side view cross-section. As shown in **6**A, physiological monitoring device **100** may include flexible body **110** coupled with rigid housing **115**. Flexible body **110** may include top substrate layer **300**, bottom substrate layer **330**, adhesive layer **340** and electrodes **350**. Electrode traces **311**, **312** are also typically part of flexible body **110** and are embedded between top substrate layer **300** and bottom substrate layer **330**, but they are not shown in FIG. **6**. Flexible body **110** forms two wings **130**, **131**, extending to either side of housing **115**, and a border **133** surrounding at least part of each wing **130**, **131**. Rigid housing **115** may include an upper housing member **140** coupled with a lower housing member **145** such that it sandwiches a portion of flexible body **110** in between and provides a watertight, sealed compartment for PCBA **120**. Upper housing member **140** may include inner trigger member **430**, and PCBA may include patient trigger member **210**. As discussed previously, lower housing member **145** may include multiple dimples **450** or divots to enhance the comfort of the monitoring device **100**.

It is desirable that PCBA **120** is sufficiently rigid to prevent bending and introducing unwanted artifact into the signal. In certain embodiments, an additional mechanism to reduce and prevent unwanted bending of PCBA **120** may be used. This mechanism is shown in FIG. **6**B. Support post **460** is integral to lower housing **145** and is positioned directly under patient trigger input **210**. During patient symptom triggering, upper housing member **140** is depressed, engaging inner trigger mechanism **430** and transmitting a force through patient trigger input **210** into PCBA **120**. The force is further transmitted through PCBA **120** and into support post **460** without creating a bending moment, thus avoiding unwanted artifact.

Referring to FIG. **7**, in some embodiments, physiological monitoring device **100** may include one or more additional, optional features. For example, in one embodiment, monitoring device **100** may include a removable liner **810**, a top label **820**, a device identifier **830** and a bottom label **840**. Liner **810** may be applied over a top surface of flexible member **110** to aid in the application of device **100** to the subject. As is described in further detail below, liner **810** may help support borders **133** of flexible body **110**, as well as wings **130**, **131**, during removal of one or more adhesive covers (not shown) that cover adhesive surface **340** before use. Liner **810** may be relative rigid and/or firm, to help support flexible body **110** during removal of adhesive covers. In various embodiments, for example, liner **810** may be made of cardboard, thick paper, plastic or the like. Liner **810** typically includes an adhesive on one side for adhering to the top surface of wings **130**, **131** of flexible body **110**.

Labels **820**, **840** may be any suitable labels and may include produce name(s), manufacturer name(s), logo(s), design(s) and/or the like. They may be removable or permanently attached upper housing member **140** and/or lower housing member **145**, although typically they will be permanently attached, to avoid unregulated reuse and/or resale of the device by an unregistered user. Device identifier **830** may be a barcode sticker, computer readable chip, RFID, or the like. Device identifier **830** may be permanently or removably attached to PCBA **120**, flexible body **110** or the like. In some embodiments, it may be beneficial to have device identifier **830** stay with PCBA **120**.

Referring now to FIGS. **8**A and **8**B, physiological monitoring device **100** generally includes hinge portions **132** at or near the juncture of each wing **130**, **131** with rigid housing **115**. Additionally, each wing **130**, **131** is typically adhered to the patient via adhesive layers **340**, while rigid body **115** is not adhered to the patient and is thus free to "float" (i.e., move up and down) over the patient's skin during movement and change of patient position. In other words, when the patient's chest contracts, rigid housing pops up or floats over the skin, thus minimizing stress on device **100**, enhancing comfort, and reducing the tendency of wings **130**, **131** to peel off of the skin. The advantage provided by the combination of the floating rigid body **115** and the adhered wings **130**, **131** is illustrated in FIGS. **8**A and **8**B. In FIG. **8**A, a patient is sleeping, and in FIG. **8**B, a patient is playing golf. In both examples, monitoring device **100** is squeezed together by the patient's body, causing rigid housing **115** to float above the skin as wings **130**, **131** move closer together. This advantage of a floating, non-attached portion of a physiological monitoring device is described in further detail in U.S. Pat. No. 8,560,046, which was previously incorporated by reference.

Referring now to FIGS. **9**A-**9**F, one embodiment of a method for applying physiological monitoring device **100** to the skin of a human subject is described. In this embodiment, before the first step shown in FIG. **9**A, the patient's skin may be prepared, typically by shaving a small portion of the skin on the left chest where device **100** will be placed and then

abrading and/or cleaning the shaved portion. As shown in FIG. **9**A, once the patient's skin is prepared, a first step of applying device **100** may include removing one or both of two adhesive covers **600** from adhesive layers **340** on the bottom surface of device **100**, thus exposing adhesive layers **340**. As illustrated in FIG. **9**B, the next step may be to apply device **100** to the skin, such that adhesive layer **340** adheres to the skin in a desired location. In some embodiments, one adhesive cover **600** may be removed, the uncovered adhesive layer **340** may be applied to the skin, and then the second adhesive cover **600** may be removed, and the second adhesive layer **340** may be applied to the skin. Alternatively, both adhesive covers **600** may be removed before applying device **100** to the skin. While adhesive covers **600** are being removed, liner **810** acts as a support for flexible body **110**, provides the physician or other user with something to hold onto, and prevents flexible body **110** and borders **133** of flexible body **110** from folding in on themselves, forming wrinkles, etc. As described above, liner **810** may be made of a relatively stiff, firm material to provide support for flexible body **110** during application of device **100** to the skin. Referring to FIG. **9**C, after device **100** has been applied to the skin, pressure may be applied to flexible body **110** to press it down onto the chest to help ensure adherence of device **100** to the skin.

In a next step, referring to FIG. **9**D, liner **810** is removed from (peeled off of) the top surface of flexible body **110**. As shown in FIG. **9**E, once liner **810** is removed, pressure may again be applied to flexible body **110** to help ensure it is adhered to the skin. Finally, as shown in FIG. **9**F, upper housing member **140** may be pressed to turn on physiological monitoring device **140**. This described method is only one embodiment. In alternative embodiments, one or more steps may be skipped and/or one or more additional steps may be added.

When a desired monitoring period has ended, such as about 14-21 days in some cases, a patient (or physician, nurse or the like) may remove physiological monitoring device **100** from the patient's skin, place device **100** in a prepaid mailing pouch, and mail device **100** to a data processing facility. At this facility, device **100** may be partially or completely disassembled, PCBA **120** may be removed, and stored physiological data, such as continuous heart rhythm information, may be downloaded from PCBA **120**. The data may then be analyzed by any suitable method and then provided to a physician in the form of a report. The physician may then discuss the report with the patient. PCBA **120** and/or other portions of device **100**, such as rigid housing **115**, may be reused in the manufacture of subsequent devices for the same or other patients. Because device **100** is built up as a combination of several removably coupled parts, various parts may be reused for the same embodiment or different embodiments of device **100**. For example, PCBA **120** may be used first in an adult cardiac rhythm monitor and then may be used a second time to construct a monitor for sleep apnea. The same PCBA **120** may additionally or alternatively be used with a differently sized flexible body **110** to construct a pediatric cardiac monitor. Thus, at least some of the component parts of device **100** may be interchangeable and reusable.

Advantageously, physiological monitoring device **100** may provide long term adhesion to the skin. The combination of the configuration of flexible and conformal body **110**, the watertight, low profile configuration of rigid housing **115**, and the interface between the two allows device **100** to compensate for stress caused as the skin of the subject stretches and bends. As a result, device **100** may be worn continuously, without removal, on a patient for as many as 14-21 days or more. In some cases, device **100** may be worn for greater or less time, but 14-21 days may often be a desirable amount of time for collecting heart rhythm data and/or other physiological signal data from a patient.

In various alternative embodiments, the shape of a particular physiological monitoring device may vary. The shape, footprint, perimeter or boundary of the device may be circular, an oval, triangular, a compound curve or the like, for example. In some embodiments, the compound curve may include one or more concave curves and one or more convex curves. The convex shapes may be separated by a concave portion. The concave portion may be between the convex portion on the rigid housing and the convex portion on the electrodes. In some embodiments, the concave portion may correspond at least partially with a hinge, hinge region or area of reduced thickness between the body and a wing.

While described in the context of a heart monitor, the device improvements described herein are not so limited. The improvements described in this application may be applied to any of a wide variety of physiological data monitoring, recording and/or transmitting devices. The improved adhesion design features may also be applied to devices useful in the electronically controlled and/or time released delivery of pharmacological agents or blood testing, such as glucose monitors or other blood testing devices. As such, the description, characteristics and functionality of the components described herein may be modified as needed to include the specific components of a particular application such as electronics, antenna, power supplies or charging connections, data ports or connections for down loading or off loading information from the device, adding or offloading fluids from the device, monitoring or sensing elements such as electrodes, probes or sensors or any other component or components needed in the device specific function. In addition or alternatively, devices described herein may be used to detect, record, or transmit signals or information related to signals generated by a body including but not limited to one or more of ECG, EEG and/or EMG.

While the above embodiments disclose the invention with respect to a data channel for collecting a single physiological signal, it is contemplated that additional data channels can be include to collect additional data, for example, device motion, device flex or bed, heart rate and/or ambient electrical noise.

Various embodiments of a physiological monitoring device and methods for using it have been disclosed above. These various embodiments may be used alone or in combination, and various changes to individual features of the embodiments may be altered, without departing from the scope of the invention. For example, the order of various method steps may in some instances be changed, and/or one or more optional features may be added to or eliminated from a described device. Therefore, the description of the embodiments provided above should not be interpreted as unduly limiting the scope of the invention as it is set forth in the claims.

Various modifications to the implementations described in this disclosure may be made, and the generic principles defined herein may be applied to other implementations without departing from the spirit or scope of this disclosure. Thus, the claims are not intended to be limited to the implementations shown herein, but are to be accorded the widest scope consistent with this disclosure, the principles and the novel features disclosed herein.

Certain features that are described in this specification in the context of separate embodiments also can be implemented in combination in a single embodiment. Conversely, various features that are described in the context of a single embodiment also can be implemented in multiple embodiments separately or in any suitable subcombination. Moreover, although features may be described above as acting in certain combinations and even initially claimed as such, one or more features from a claimed combination can in some cases be excised from the combination, and the claimed combination may be directed to a subcombination or variation of a subcombination.

Similarly, while operations are depicted in the drawings in a particular order, such operations need not be performed in the particular order shown or in sequential order, or that all illustrated operations be performed, to achieve desirable results. Further, the drawings may schematically depict one more example processes in the form of a flow diagram. However, other operations that are not depicted can be incorporated in the example processes that are schematically illustrated. For example, one or more additional operations can be performed before, after, simultaneously, or between any of the illustrated operations. Moreover, the separation of various system components in the embodiments described above should not be interpreted as requiring such separation in all embodiments. Additionally, other embodiments are within the scope of the following claims. In some cases, the actions recited in the claims can be performed in a different order and still achieve desirable results.

What is claimed is:

1. A physiological monitoring device configured to monitor cardiac rhythm data of a patient, the physiological monitoring device comprising:

a first housing portion and a second housing portion, wherein the first housing portion detachably couples to the second housing portion;

a first spring contact configured to electrically couple a battery to a circuit board assembly housed within the first housing portion;

a flexible substrate coupled to the second housing portion, wherein the flexible substrate comprises a border portion that is thinner than an interior portion of the flexible substrate;

an electrode embedded within a portion of the flexible substrate and configured to detect physiological signals of the patient to obtain the cardiac rhythm data; and

a flexible electrode trace embedded in the flexible substrate and configured to electrically couple the electrode to the circuit board assembly, wherein at least a portion of the flexible electrode trace is in electrical contact with a second spring contact, and wherein the second spring contact is further configured to electrically couple the flexible electrode trace to the circuit board assembly.

2. The physiological monitoring device of claim **1**, wherein the second spring contact is in physical contact with an electrocardiogram circuit interface.

3. The physiological monitoring device of claim **1**, further comprising a support post configured such that force from interaction with a trigger is applied to the support post.

4. The physiological monitoring device of claim **3**, wherein the force from interaction with the trigger is transmitted through the circuit board assembly to the support post.

5. The physiological monitoring device of claim **3**, wherein the support post is further configured to remain rigid during depression of the trigger.

6. The physiological monitoring device of claim **3**, wherein the support post is positioned below the trigger.

7. The physiological monitoring device of claim **3**, wherein the support post is positioned between the circuit board assembly and a housing portion.

8. The physiological monitoring device of claim **7**, wherein the housing portion comprises the second housing portion.

9. The physiological monitoring device of claim **7**, wherein the support post is integral with the housing portion.

10. The physiological monitoring device of claim **3**, wherein the force is transmitted to the support post without creating a bending moment.

11. The physiological monitoring device of claim **1**, wherein the first housing portion comprises a rigid housing configured to prevent deformation of the circuit board assembly in response to movement of the patient.

12. The physiological monitoring device of claim **1**, wherein the flexible substrate comprises an electrode-supporting section.

13. The physiological monitoring device of claim **1**, further comprising a gasket configured to make a housing watertight, wherein the housing comprises at least the first housing portion and the second housing portion.

14. The physiological monitoring device of claim **1**, wherein the flexible electrode trace is sandwiched between a first layer and a second layer of the flexible substrate.

15. The physiological monitoring device of claim **1**, wherein the circuit board assembly is substantially rigid.

16. The physiological monitoring device of claim **1**, further comprising a trigger configured to cause a signal to be relayed to the circuit board assembly in response to user interaction with the trigger.

17. The physiological monitoring device of claim **16**, wherein the trigger comprises a button.

18. The physiological monitoring device of claim **1**, further comprising an adhesive layer located on at least a portion of the flexible substrate and configured to adhere to skin of the patient.

19. The physiological monitoring device of claim **18**, wherein the adhesive layer is configured to adhere to the skin of the patient for at least 7 days enabling the physiological monitoring device to monitor the cardiac rhythm data of the patient for at least 7 days.

20. The physiological monitoring device of claim **1**, further comprising an LED indicator configured to indicate activation.

21. The physiological monitoring device of claim **1**, further comprising a second electrode embedded within a second portion of the flexible substrate.

22. The physiological monitoring device of claim **1**, wherein the flexible electrode trace electrically couples the electrode to the circuit board assembly via the second spring contact.

* * * * *

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Bahney et al.

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(54) **PHYSIOLOGICAL MONITORING DEVICE**

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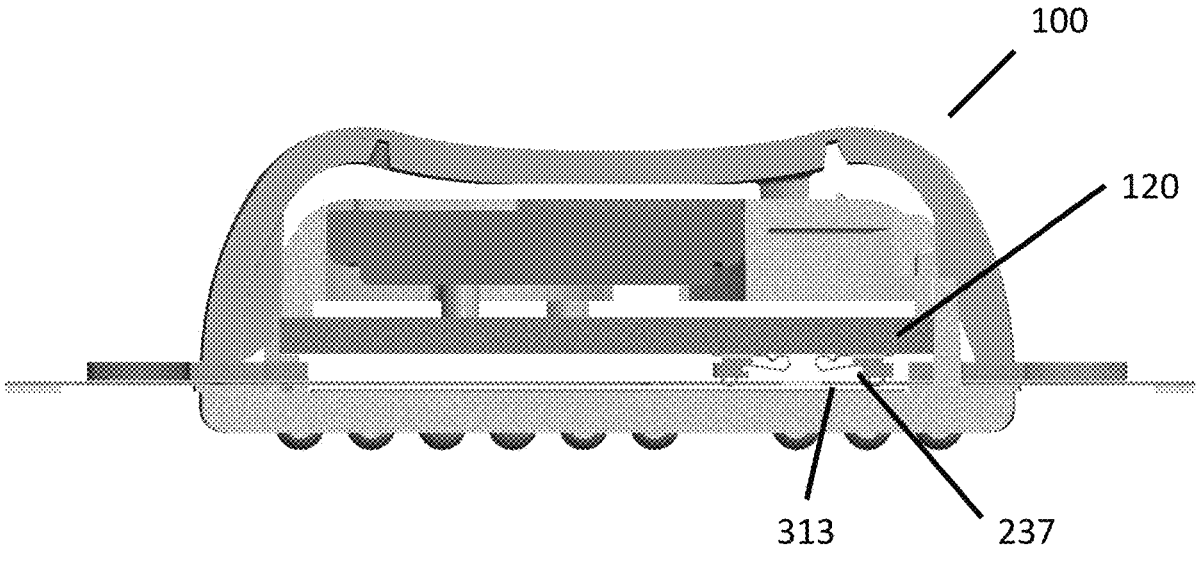
(57) **ABSTRACT**

The present invention relates to a physiological monitoring device. Some embodiments of the invention allow for long-term monitoring of physiological signals. Further embodiments may also allow for the monitoring of secondary signals such as motion.

25 Claims, 17 Drawing Sheets



Related U.S. Application Data

No. 16/786,831, filed on Feb. 10, 2020, now Pat. No. 11,627,902, which is a continuation of application No. 16/397,651, filed on Apr. 29, 2019, now Pat. No. 10,555,683, which is a continuation of application No. 16/006,719, filed on Jun. 12, 2018, now Pat. No. 10,271,754, which is a continuation of application No. 14/162,656, filed on Jan. 23, 2014, now abandoned.

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USPC 438/50–51, 53
See application file for complete search history.

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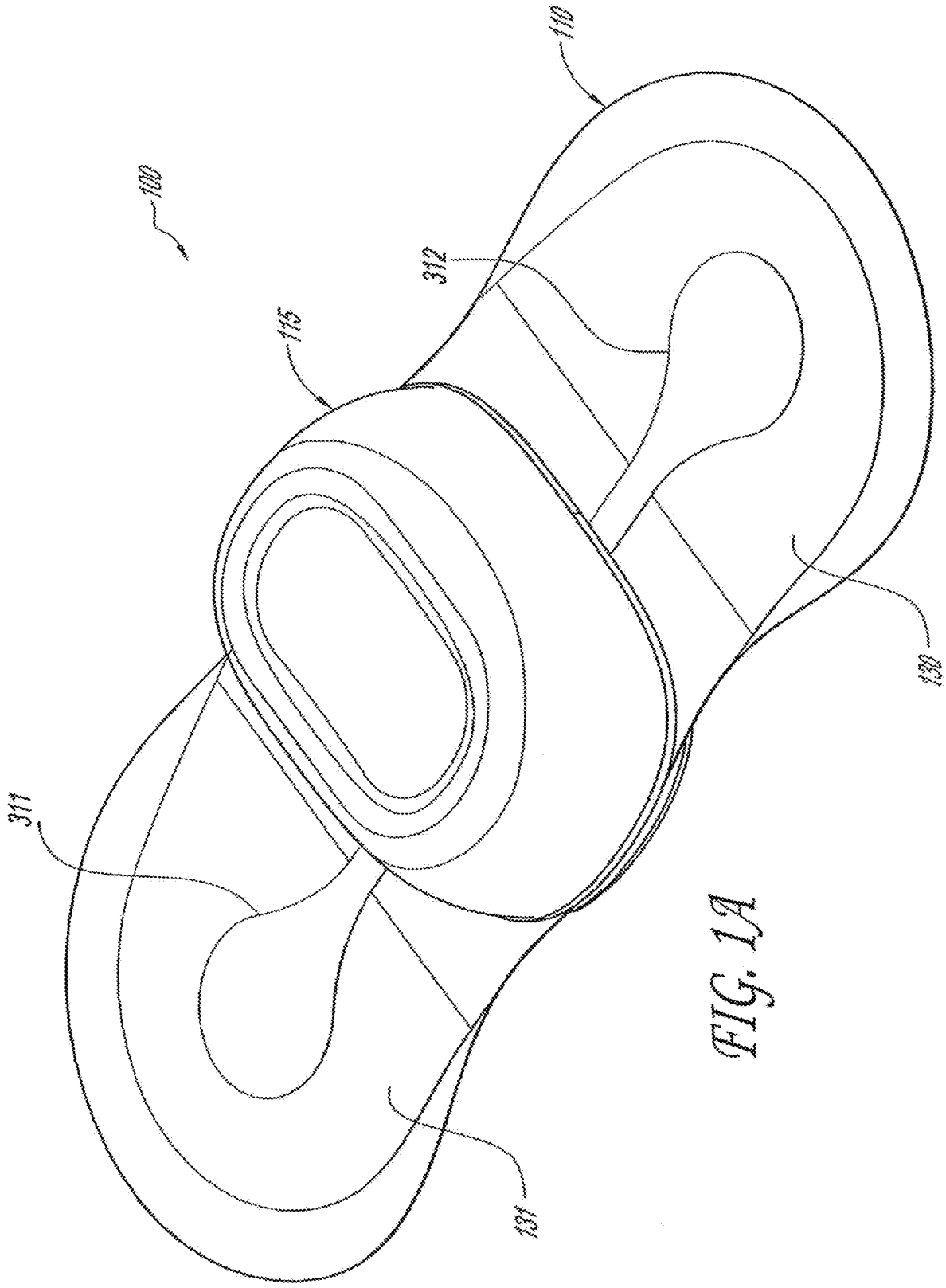

FIG. 1A

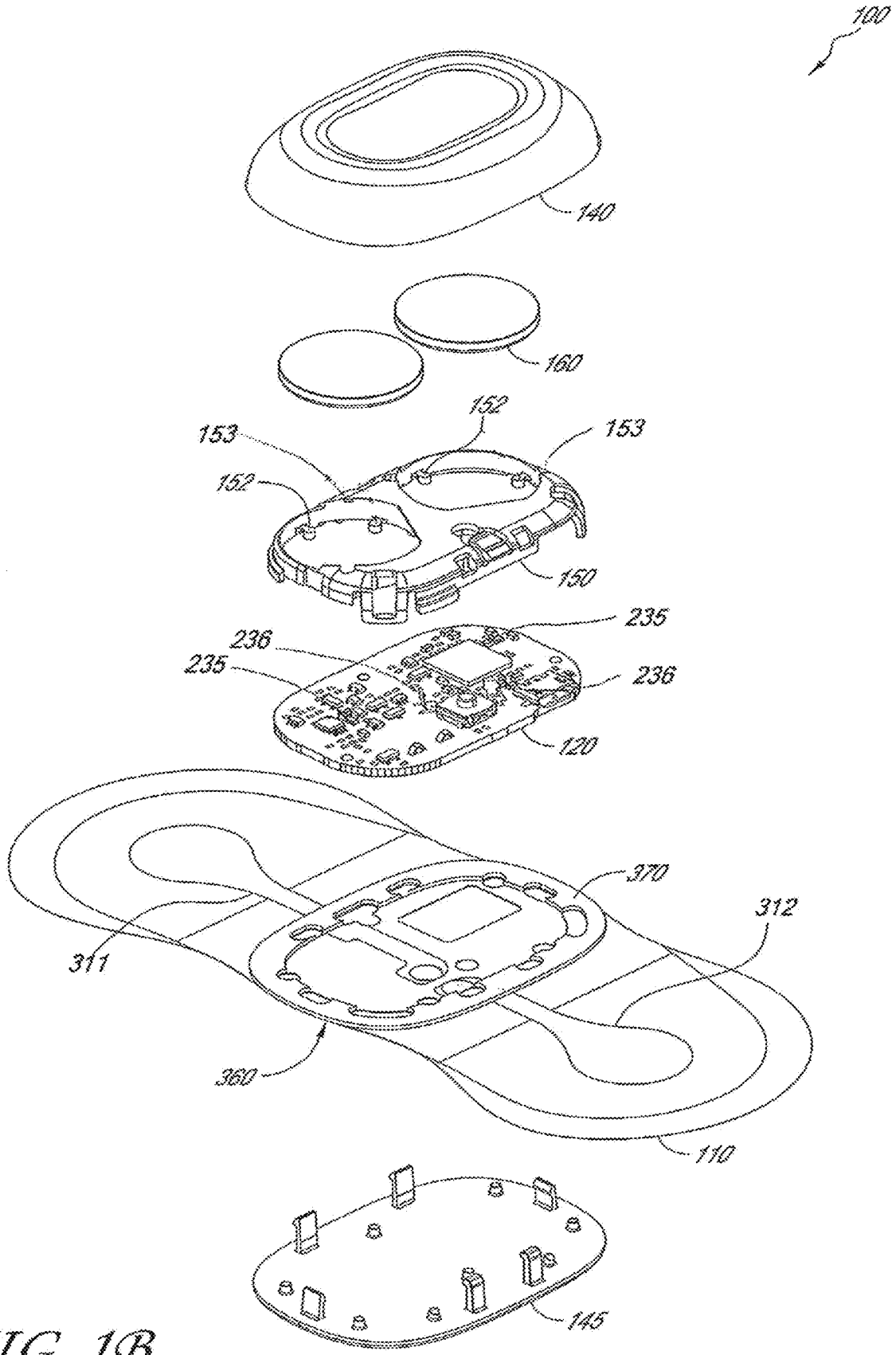
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FIG. 1B

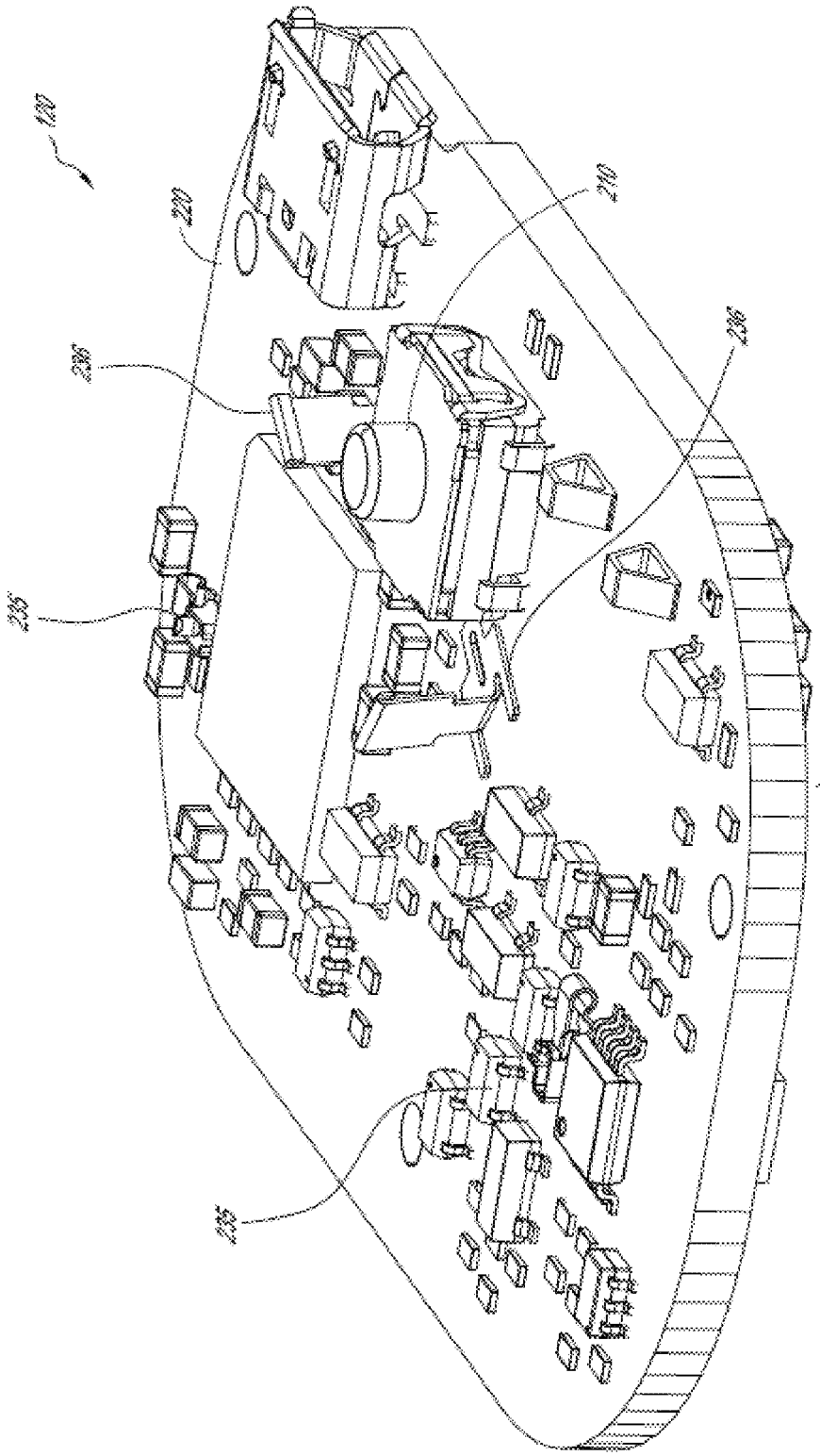
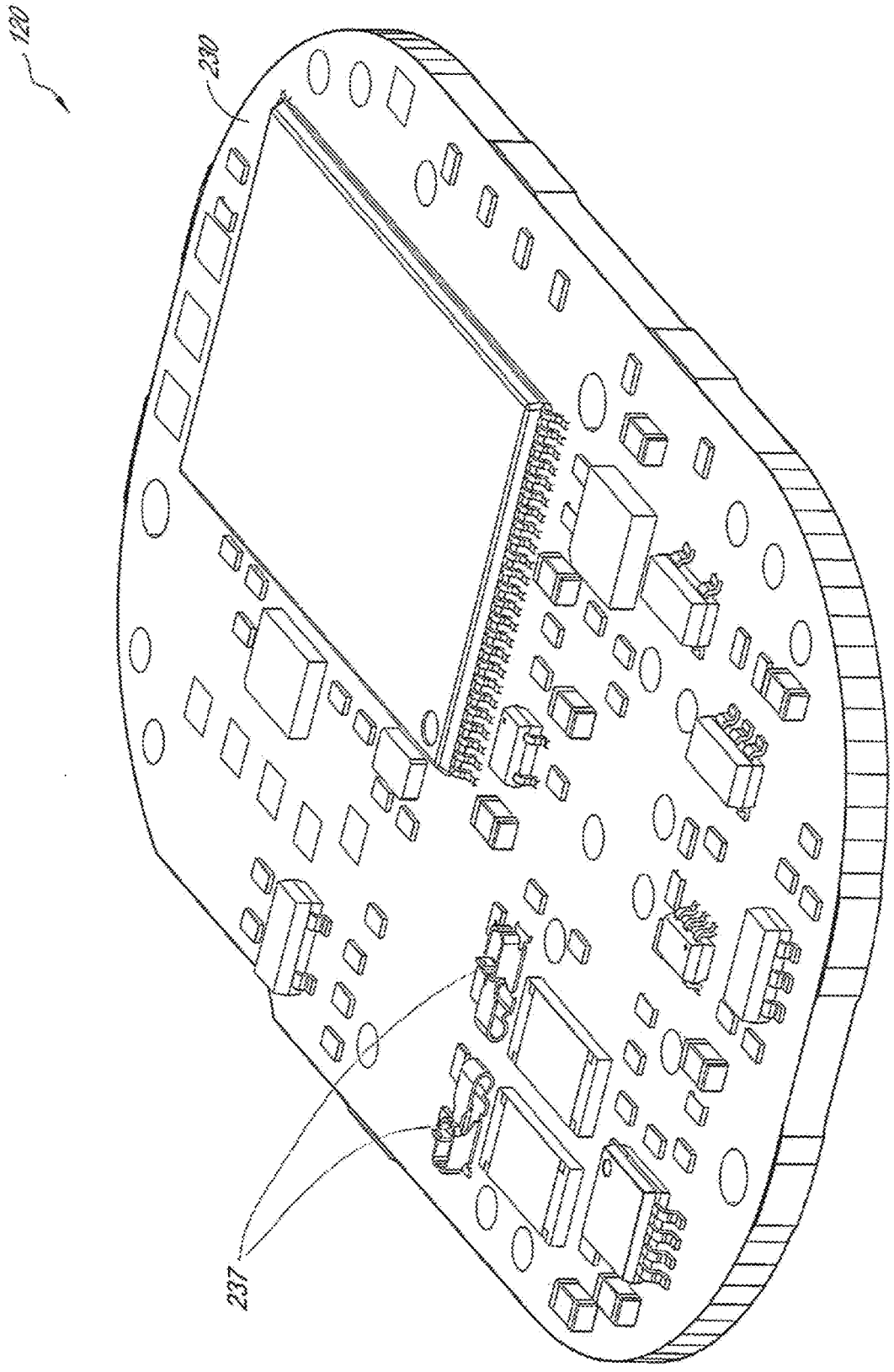


FIG. 2A



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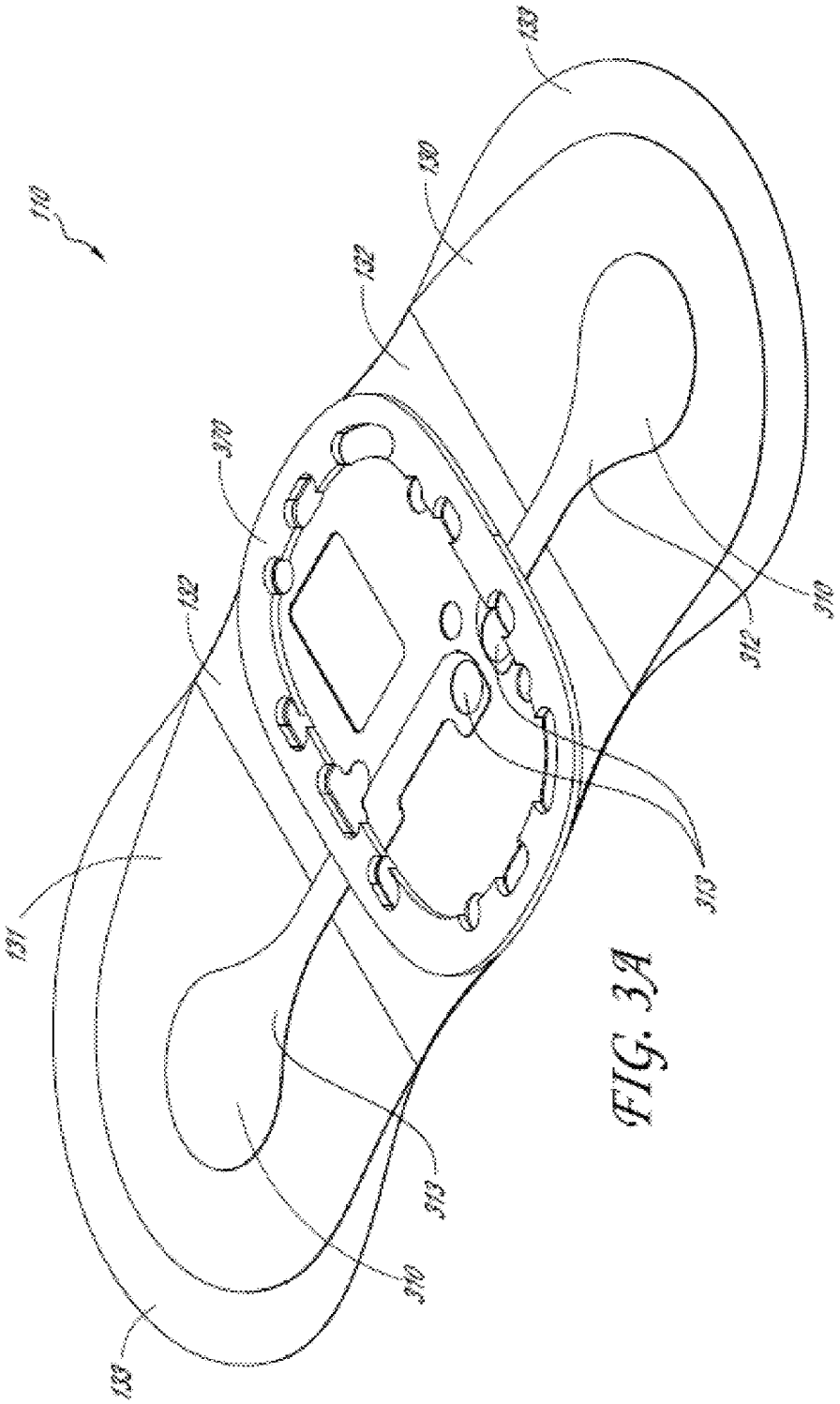
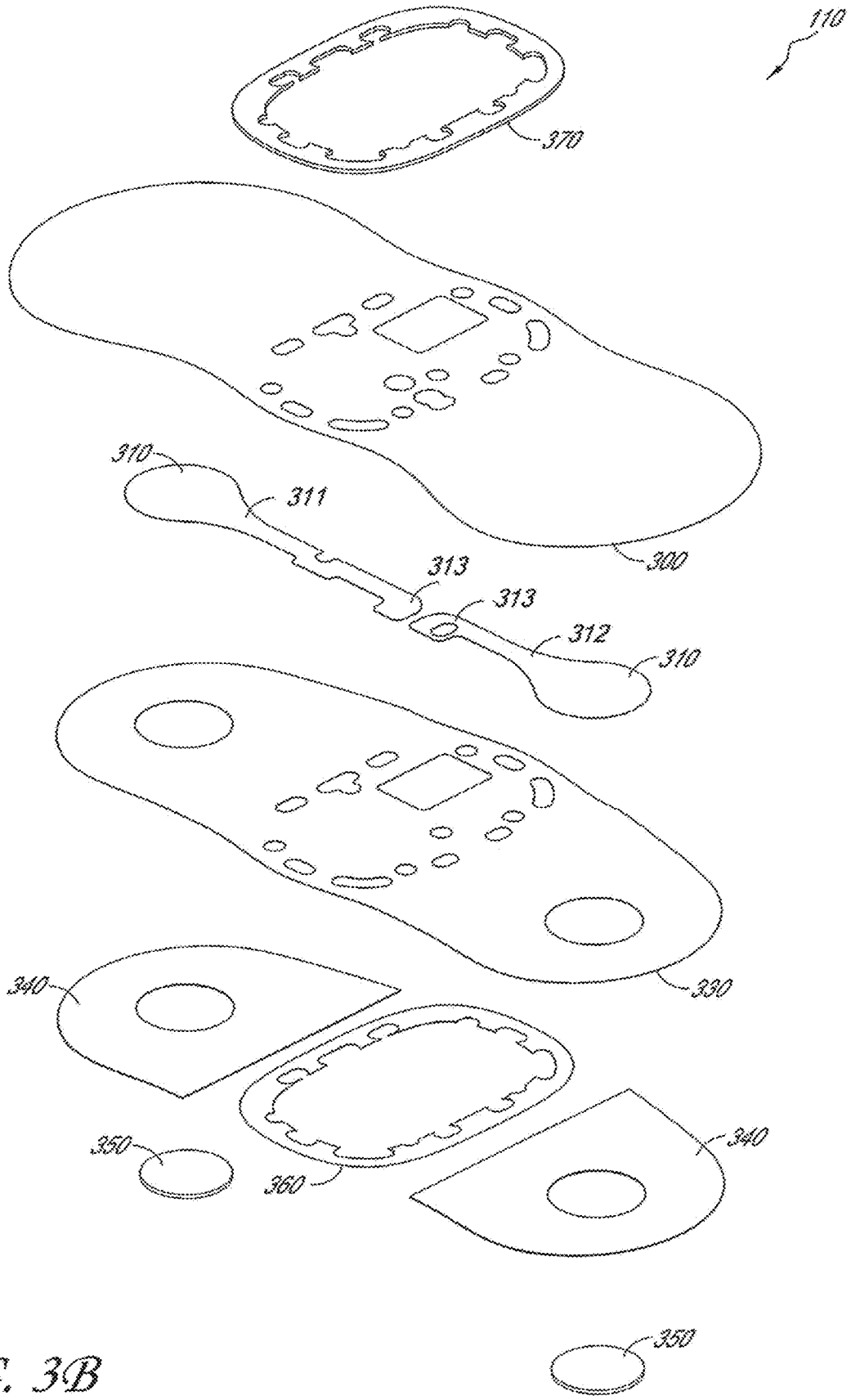


FIG. 3A



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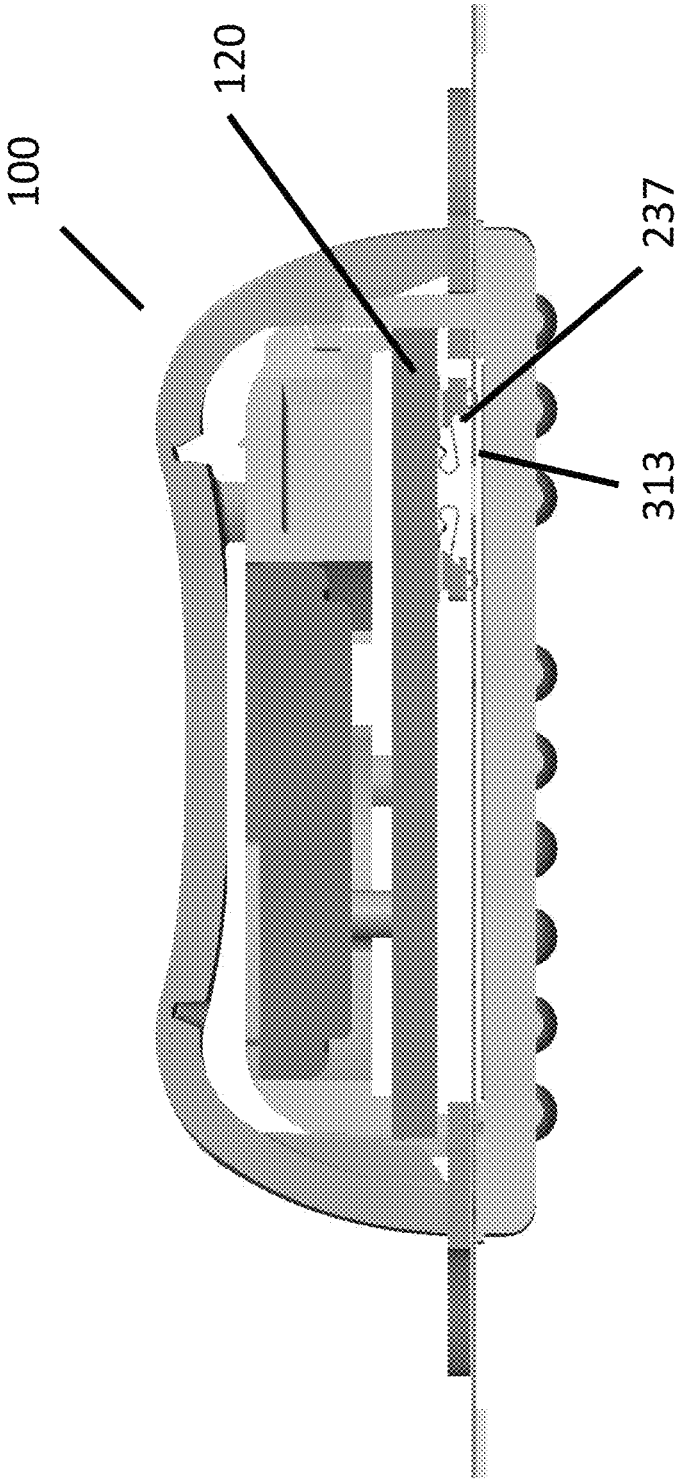


FIG. 3C

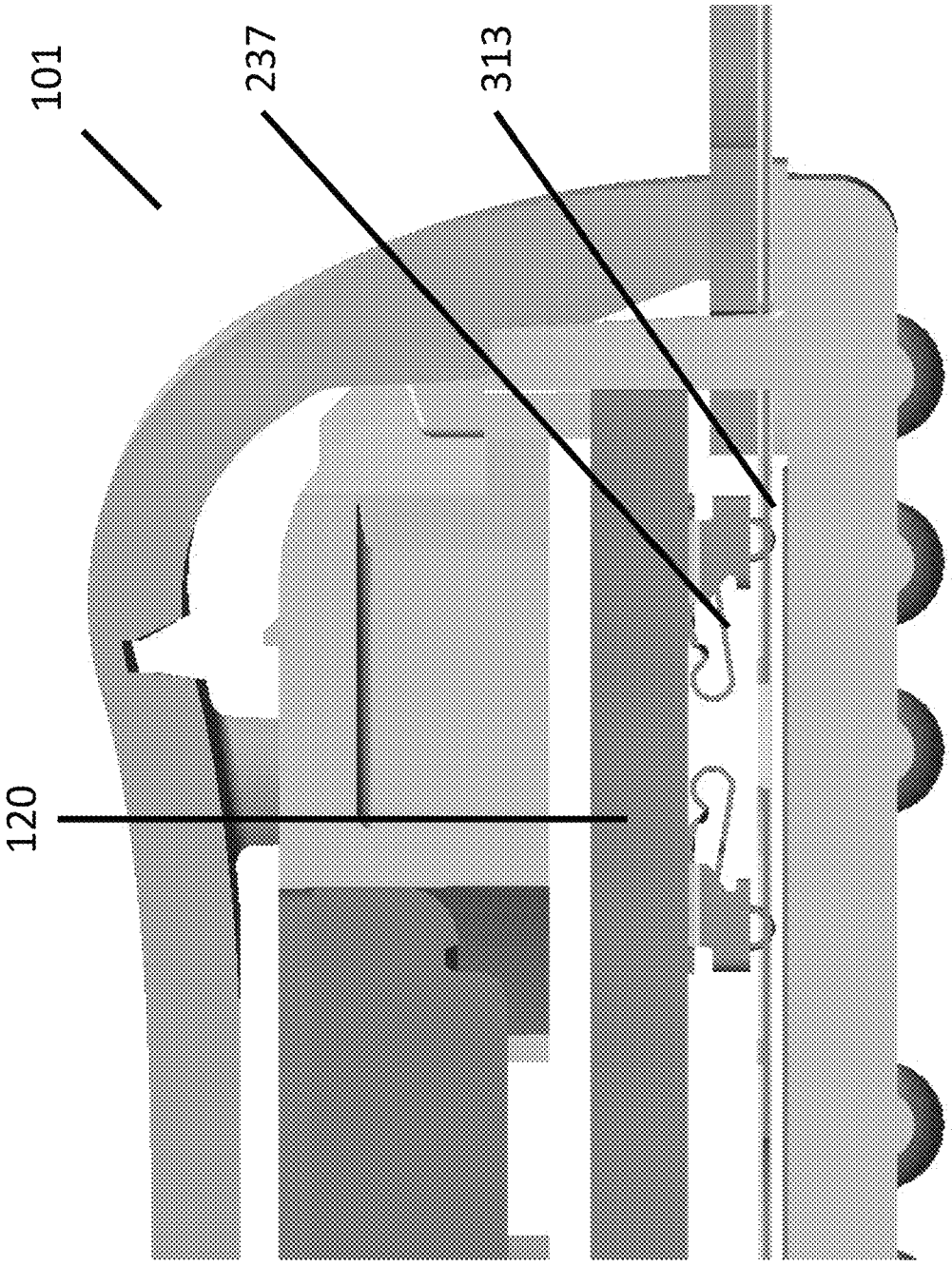


FIG. 3D

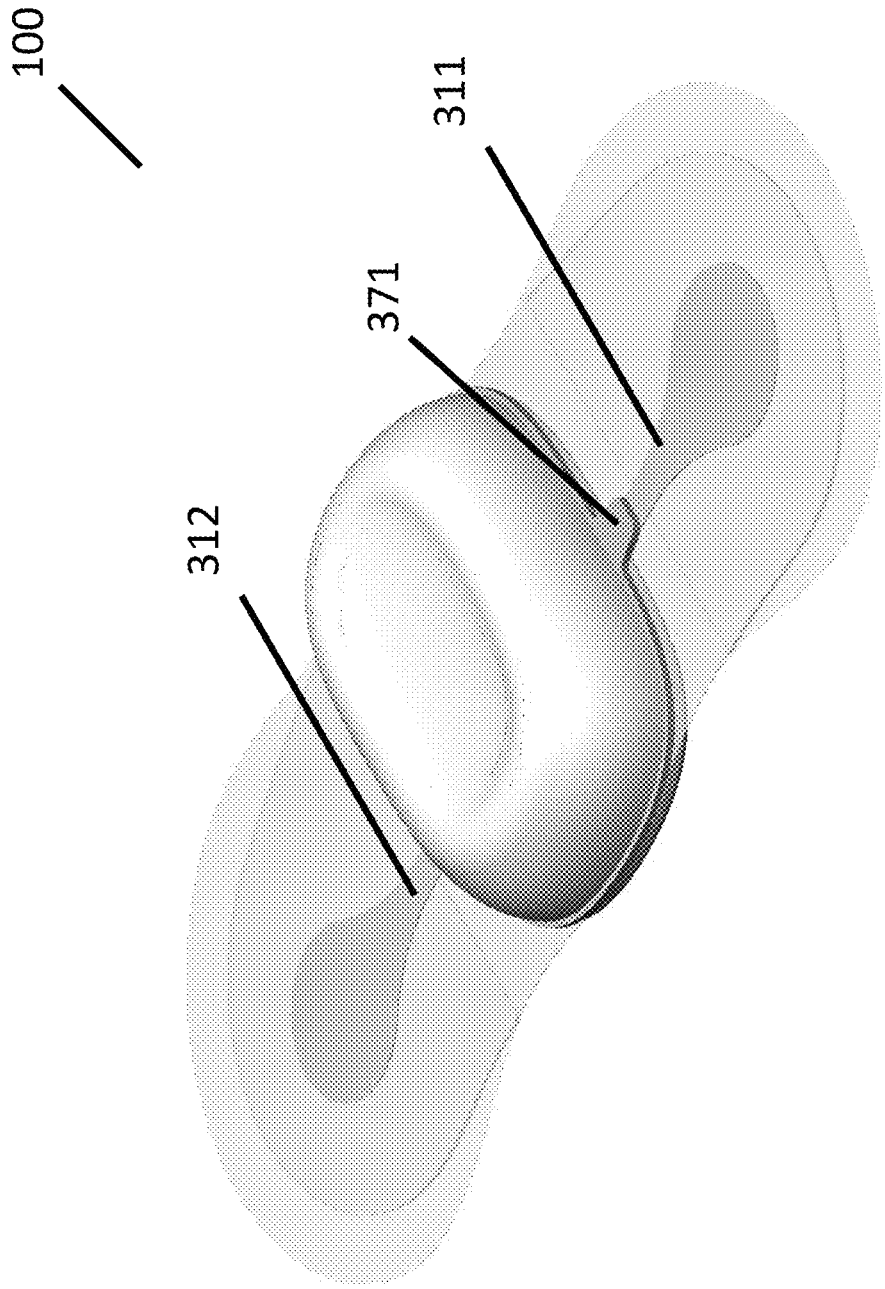


FIG. 3E

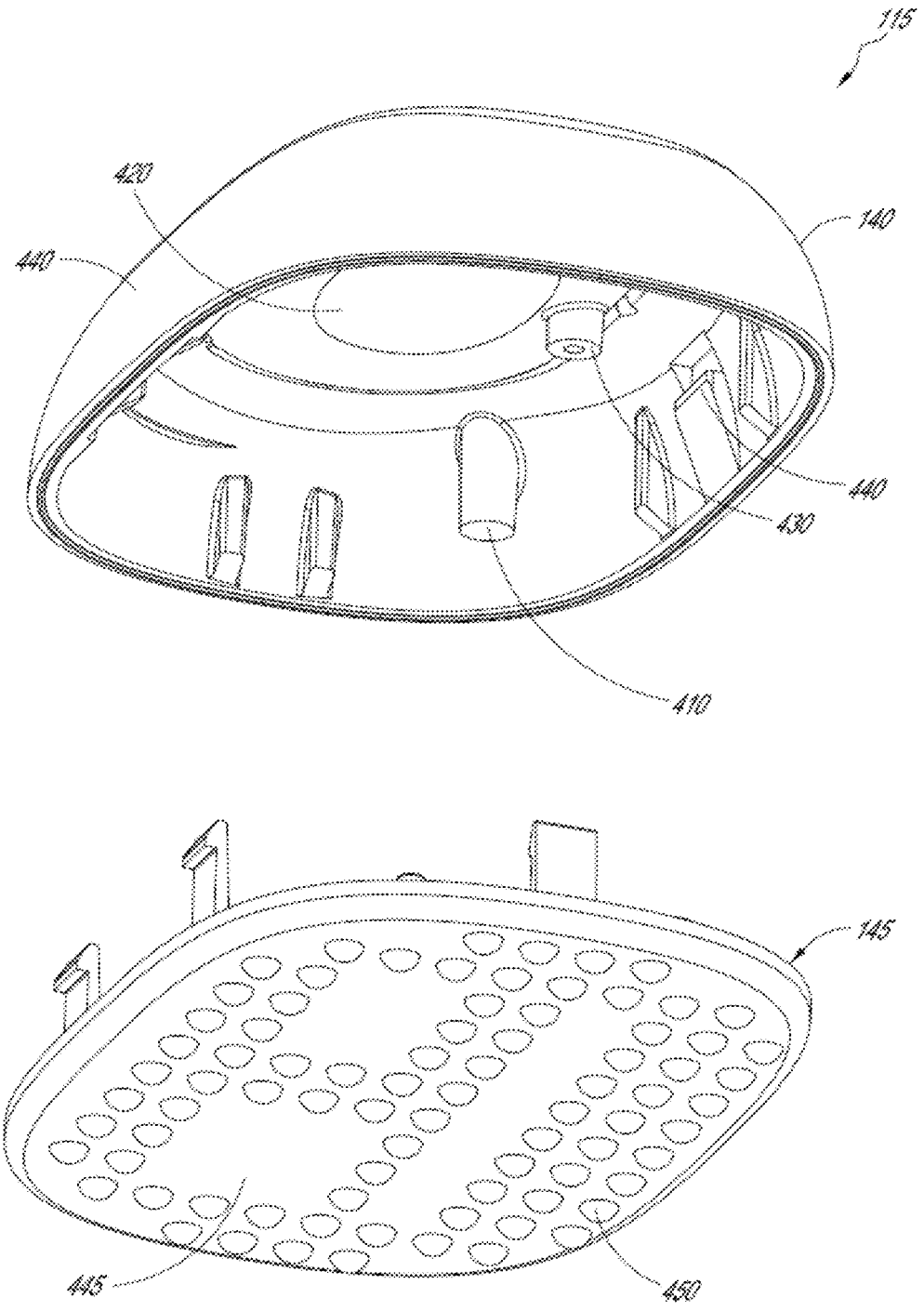
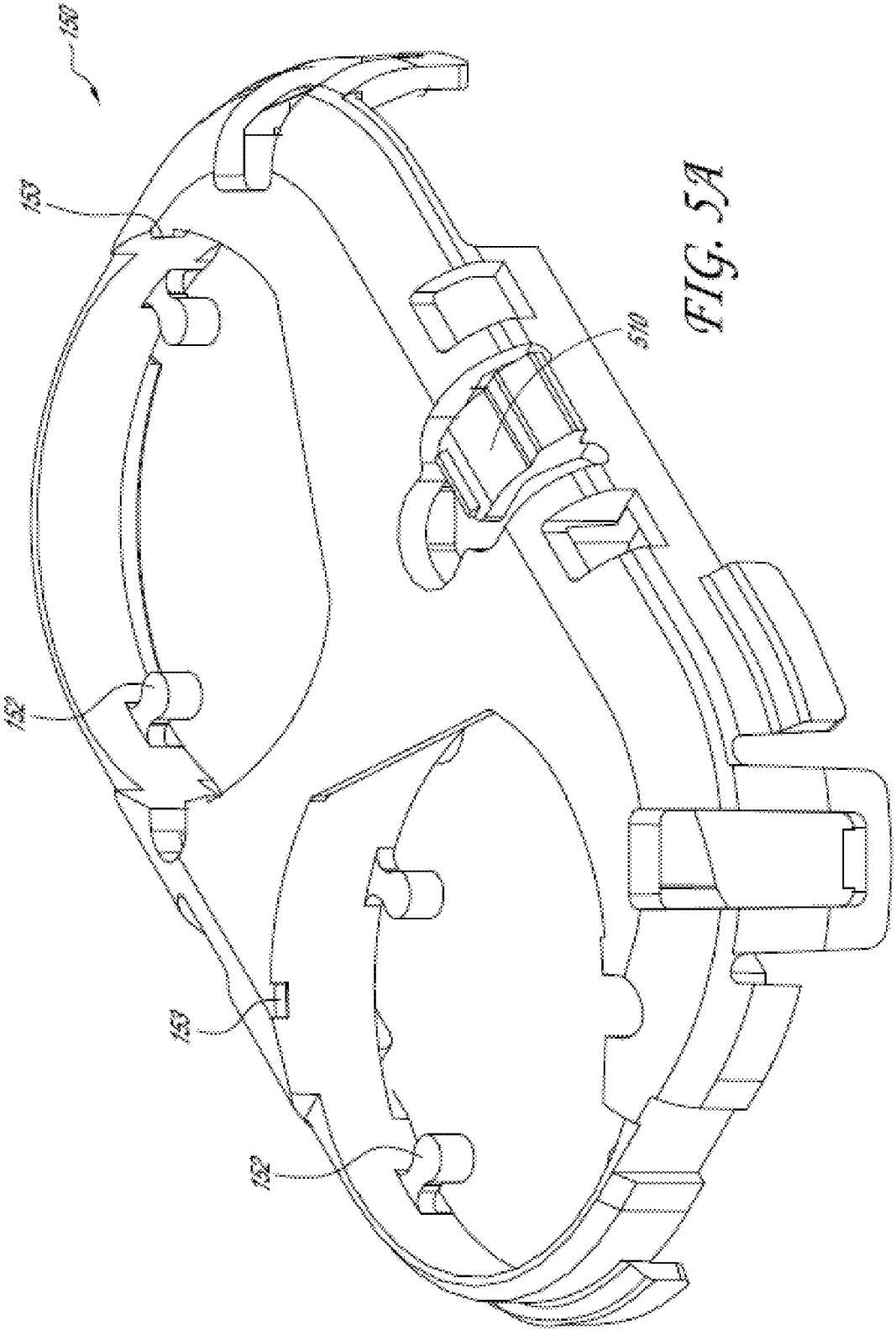


FIG. 4



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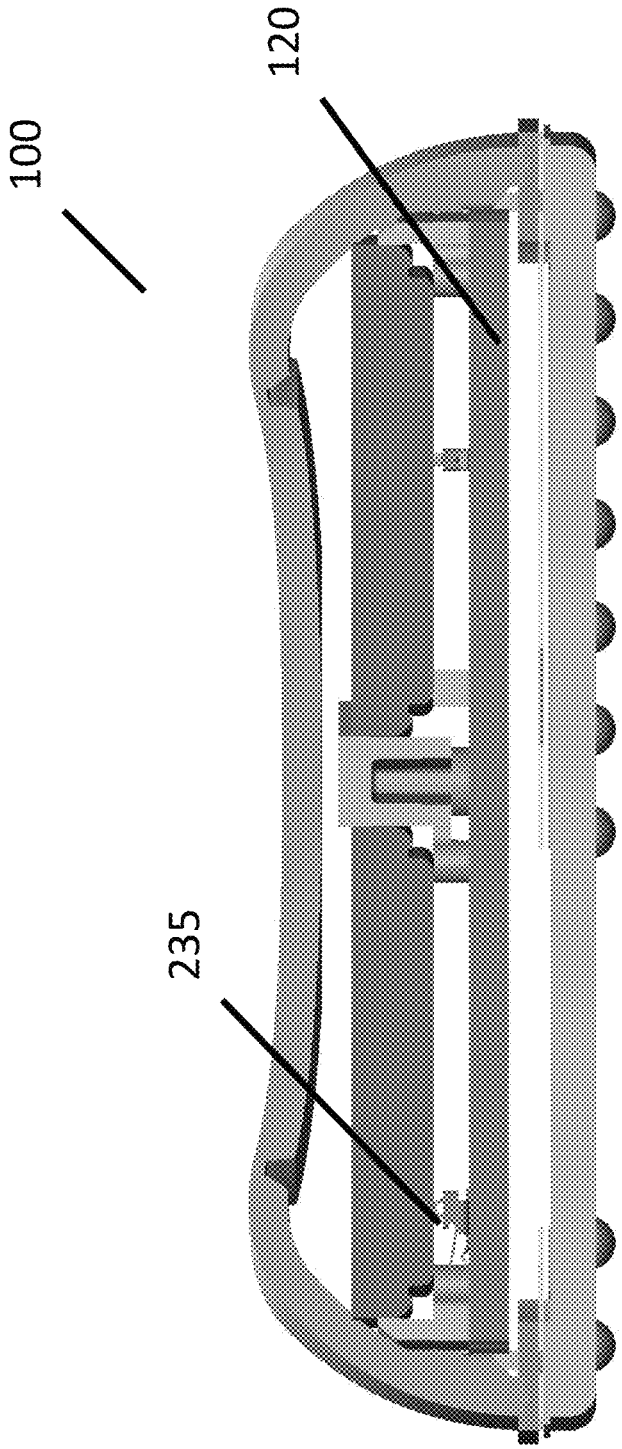


FIG. 5B

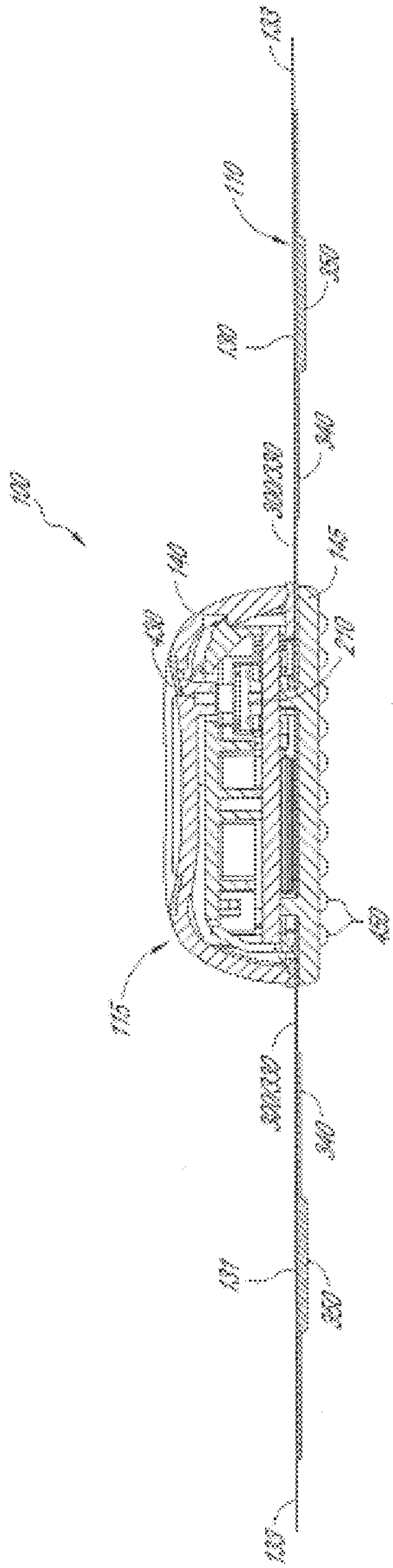
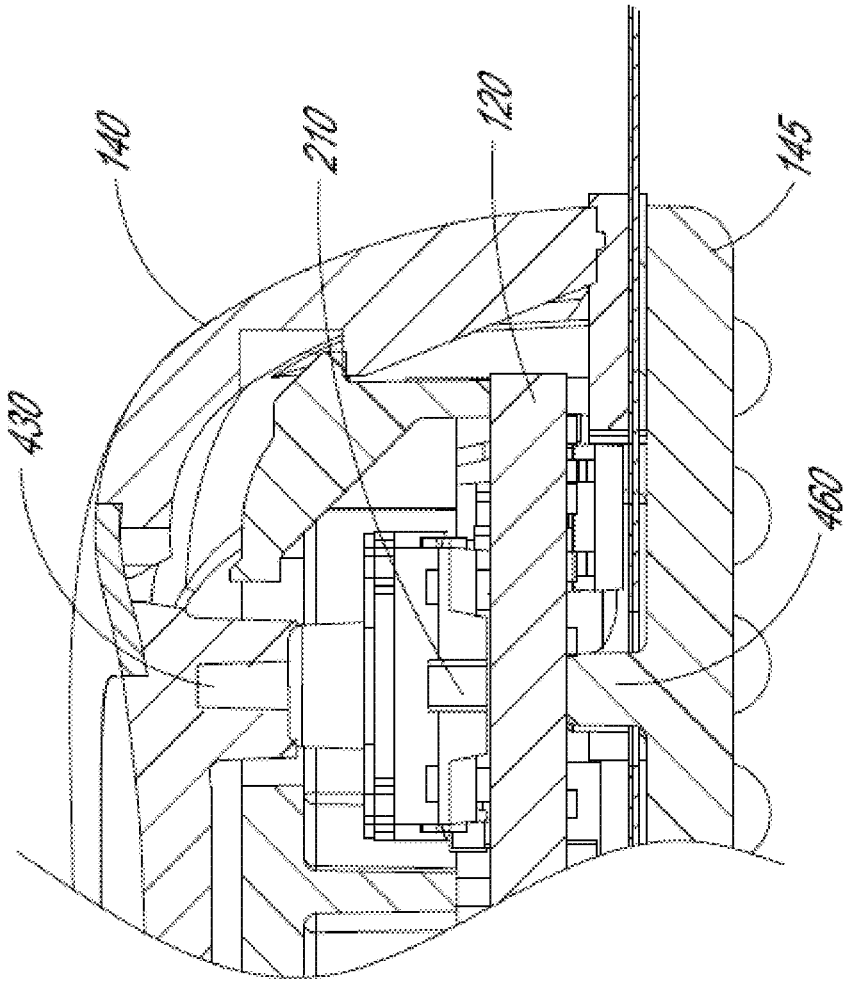


FIG. 6A



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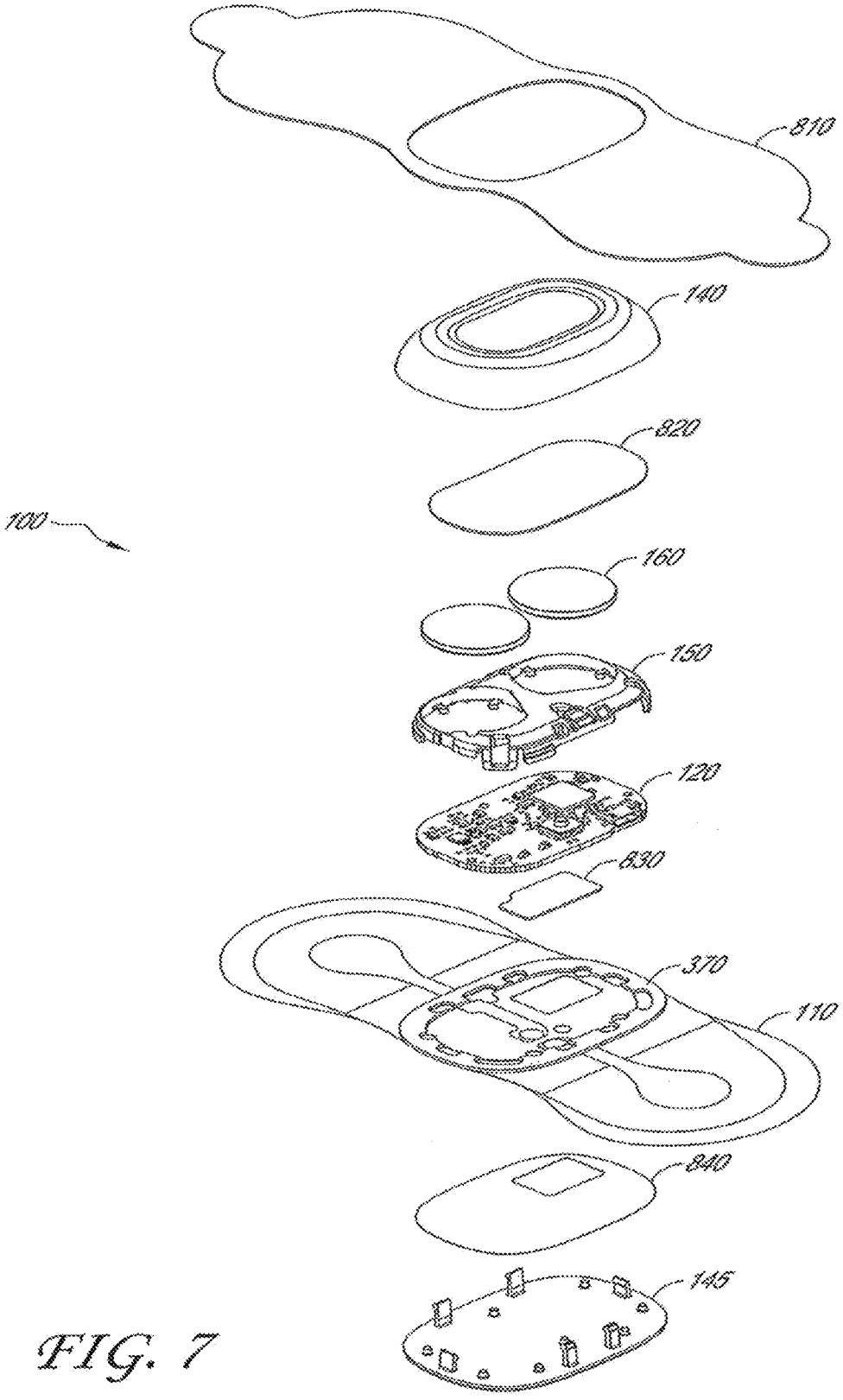

FIG. 7

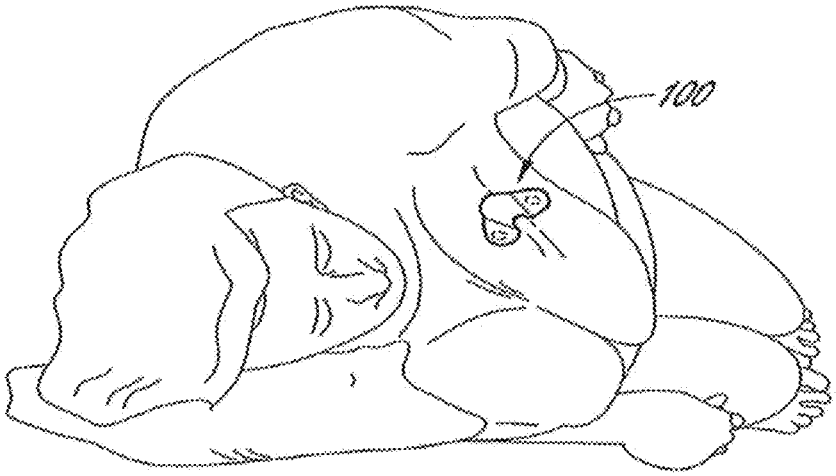

FIG. 8A

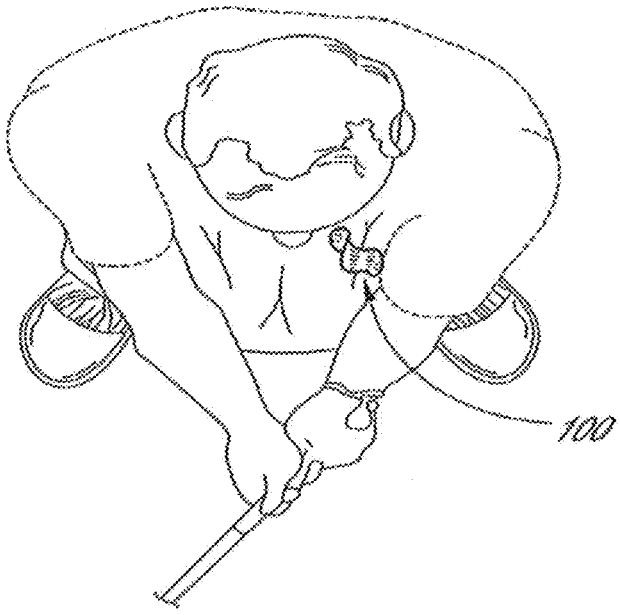

FIG. 8B

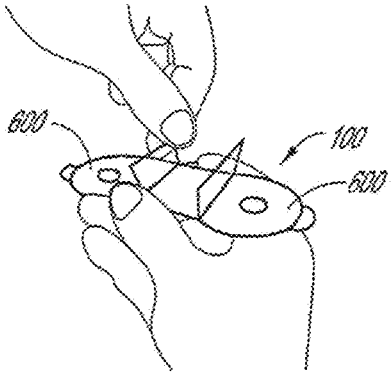

FIG. 9A

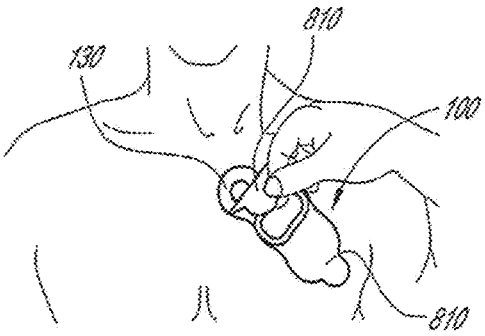

FIG. 9D

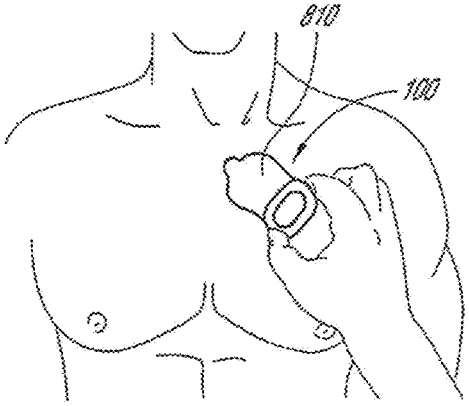

FIG. 9B

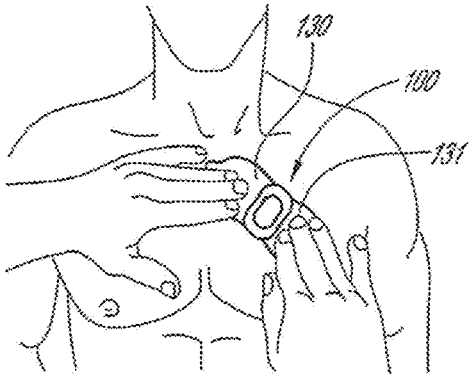

FIG. 9E

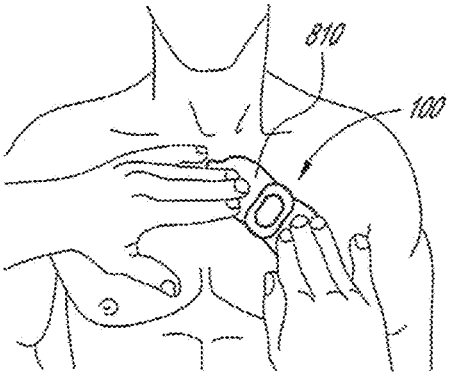

FIG. 9C

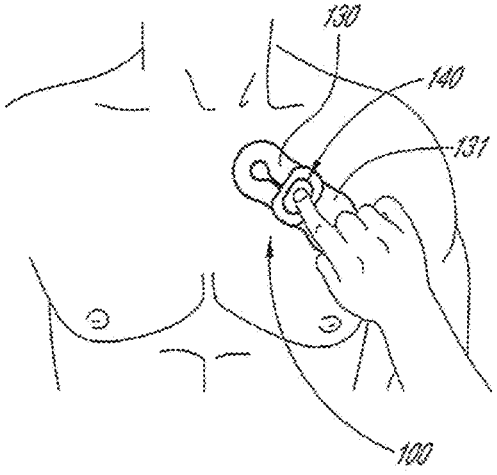

FIG. 9F

PHYSIOLOGICAL MONITORING DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 18/301,881, filed Apr. 17, 2023, which is a continuation of U.S. patent application Ser. No. 16/786,831, filed Feb. 10, 2020, which is a continuation of U.S. patent application Ser. No. 16/397,651, filed Apr. 29, 2019, which is a continuation of U.S. patent application Ser. No. 16/006,719, filed Jun. 12, 2018, which is a continuation of Ser. No. 14/162,656, filed, Jan. 23, 2014, which claims the benefit of U.S. Provisional Application No. 61/756,326, filed Jan. 24, 2013, entitled PHYSIOLOGICAL MONITORING DEVICE. The contents of the aforementioned applications are hereby incorporated by reference in their entireties as if fully set forth herein. The benefit of priority to the foregoing provisional application is claimed under the appropriate legal basis, including, without limitation, under 35 U.S.C. § 119(e).

BACKGROUND

Field of the Invention

The invention relates generally to medical devices. More specifically, the invention relates to a physiological monitoring device and method for use.

Description of the Related Art

Abnormal heart rhythms, or arrhythmias, may cause various types of symptoms, such as loss of-consciousness, palpitations, dizziness, or even death. An arrhythmia that causes such symptoms is often an indicator of significant underlying heart disease. It is important to identify when such symptoms are due to an abnormal heart rhythm, since treatment with various procedures, such as pacemaker implantation or percutaneous catheter ablation, can successfully ameliorate these problems and prevent significant symptoms and death.

Since the symptoms listed above can often be due to other, less serious causes, a key challenge is to determine when any of these symptoms are due to an arrhythmia. Oftentimes, arrhythmias occur infrequently and/or episodically, making rapid and reliable diagnosis difficult. Currently, cardiac rhythm monitoring is primarily accomplished through the use of devices, such as Holter monitors, that use short-duration (<1 day) electrodes affixed to the chest. Wires connect the electrodes to a recording device, usually worn on a belt. The electrodes need daily changing and the wires are cumbersome. The devices also have limited memory and recording time. Wearing the device interferes with patient movement and often precludes performing certain activities while being monitored, such as bathing. All of these limitations severely hinder the diagnostic usefulness of the device, the compliance of patients using the device and the likelihood of capturing all important information. Lack of compliance and the shortcomings of the devices often lead to the need for additional devices, follow-on monitoring or other tests to make a correct diagnosis.

Current methods to correlate symptoms with the occurrence of arrhythmias, including the use of cardiac rhythm monitoring devices, such as Holter monitors and cardiac event recorders, are often not sufficient to allow an accurate diagnosis to be made. In fact, Holter monitors have been shown to not lead to a diagnosis up to 90% of the time ("Assessment of the Diagnostic Value of 24-Hour Ambulatory Electrocariographic Monitoring", by DE Ward et al. Biotelemetry Patient Monitoring, vol. 7, published in 1980).

Additionally, the medical treatment process to actually obtain a cardiac rhythm monitoring device and initiate monitoring is typically very complicated. There are usually numerous steps involved in ordering, tracking, monitoring, retrieving, and analyzing the data from such a monitoring device. In most cases, cardiac monitoring devices used today are ordered by a cardiologist or a cardiac electrophysiologist (EP), rather than the patient's primary care physician (PCP). This is of significance since the PCP is often the first physician to see the patient and determine that the patient's symptoms could be due to an arrhythmia. After the patient sees the PCP, the PCP will make an appointment for the patient to see a cardiologist or an EP. This appointment is usually several weeks from the initial visit with the PCP, which in itself leads to a delay in making a potential diagnosis as well as increases the likelihood that an arrhythmia episode will occur and go undiagnosed. When the patient finally sees the cardiologist or EP, a cardiac rhythm monitoring device will usually be ordered. The monitoring period can last 24-48 hours (Holter monitor) or up to a month (cardiac event monitor or mobile telemetry device). Once the monitoring has been completed, the patient typically must return the device to the clinic, which itself can be an inconvenience. After the data has been processed by the monitoring company or by a technician on-site at a hospital or office, a report will finally be sent to the cardiologist or EP for analysis. This complex process results in fewer patients receiving cardiac rhythm monitoring than would ideally receive it.

To address some of these issues with cardiac monitoring, the assignee of the present application developed various embodiments of a small, long-term, wearable, physiological monitoring device. One embodiment of the device is the Zio® Patch (www.irhythmtech.com). Various embodiments are also described, for example, in U.S. Pat. Nos. 8,150,502, 8,160,682 8,244,335, 8,560,046, and 8,538,503, the full disclosures of which are hereby incorporated by reference. Generally, the physiological monitors described in the above references fit comfortably on a patient's chest and are designed to be worn for at least one week and typically two to three weeks. The monitors detect and record cardiac rhythm signal data continuously while the device is worn, and this cardiac rhythm data is then available for processing and analysis.

These smaller, long-term physiological monitoring devices provided many advantages over prior art devices. At the same time, further improvements are desired. One of the most meaningful areas for improvement exists around increasing fidelity of the recorded ECG signal. This is particularly important for single-channel embodiments where a second vector of ECG is not available to clarify whether aberrances in signal are due to arrhythmia or signal artifact. Increases in signal to noise ratio as well as reduction of motion artifact improve efficiency in both algorithmic and human analysis of the recorded ECG signal.

Signal quality is important throughout the duration of wear, but it is particularly critical where the patient marks the record, indicating an area of symptomatic clinical significance. Marking the record is most easily enabled through a trigger located on the external surface of the device. However, since the trigger is part of a skin-contacting platform with integrated electrodes, the patient can introduce significant motion artifacts when feeling for the trigger.

A desirable device improvement would be a symptom trigger that can be activated with minimal addition of motion artifact.

Secondly, patient compliance and device adhesion performance are two factors that govern the duration of the ECG record and consequently the diagnostic yield. Compliance can be increased by improving the patient's wear experience, which is affected by wear comfort, device appearance and the extent to which the device impedes the normal activities of daily living. Given that longer ECG records provide greater diagnostic yield and hence value, improvements to device adhesion and patient compliance are desirable.

Finally, it is desirable for the device to be simple and cost effective to manufacture, enabling scalability at manufacturing as well as higher quality due to repeatability in process. Simplicity of manufacture can also lead to ease of disassembly, which enables the efficient recovery of the printed circuit board for quality-controlled reuse in another device. Efficient reuse of this expensive component is critical for decreasing the cost of the diagnostic monitor. At least some of the objectives will be met by the embodiments described below.

BRIEF SUMMARY

Embodiments described herein are directed to a physiological monitoring device that may be worn continuously and comfortably by a human or animal subject for at least one week or more and more typically two to three weeks or more. In one embodiment, the device is specifically designed to sense and record cardiac rhythm (i.e., electrocardiogram, ECG) data, although in various alternative embodiments one or more additional physiological parameters may be sensed and recorded. The physiological monitoring device includes a number of features to facilitate and/or enhance the patient experience, to make diagnosis of cardiac arrhythmias more accurate, and to make manufacture of the device more simple and cost effective.

In some embodiments, an electronic device for monitoring physiological signals in a mammal comprises:

- at least two flexible wings extending laterally from a rigid housing, wherein the flexible wings comprise a first set of materials which enable the wings to conform to a surface of the mammal and the rigid housing comprises a second set of materials;
- a printed circuit board assembly housed within the rigid housing, wherein the rigid housing is configured to prevent deformation of the printed circuit board in response to movement of the mammal;
- at least two electrodes embedded within the flexible wings, the electrodes configured to provide conformal contact with the surface of the mammal and to detect the physiological signals of the mammal;
- at least two electrode traces embedded within the wings and mechanically decoupled from the rigid housing, the electrode traces configured to provide conformal contact with the surface of the mammal and transmit electrical signals from the electrodes to the printed circuit board assembly; and,
- at least one hinge portion connecting the wings to the rigid housing, the hinge portions configured to flex freely at the area where it is joined to the rigid housing.

In certain embodiments, each wing may comprise an adhesive. In embodiments, the electrodes can be in the same plane as the adhesive. In certain embodiments, each wing comprises at least one rim, wherein the rim is thinner than an adjacent portion of each wing. The rigid housing may further comprise dimples configured to allow for airflow between the rigid housing and the surface of the mammal. In certain embodiments, the rim is configured to prevent the release of a portion of the wing from the surface of the mammal. In some embodiments, an electronic device for monitoring physiological systems may comprise a measuring instrument configured to detect motion signals in at least one axis. This measuring instrument may be an accelerometer that can be configured to detect motion signals in three axes.

In embodiments, the motion signals can be collected in time with the physiological signals. In certain embodiments, a motion artifact is identified when the physiological signals and the motion signals match. Further embodiments may call for an event trigger coupled to the printed circuit board assembly. In some embodiments, the event trigger input is supported by the rigid housing so as to prevent mechanical stress on the printed circuit board when the trigger is activated. The event trigger may be concave and larger than a human finger such that the event trigger is easily located. In certain embodiments, the electrode traces are configured to minimize signal distortion during movement of the mammal. In particular embodiments, gaskets may be used as a means for sealable attachment to the rigid housing.

In certain embodiments, a method for monitoring physiological signals in a mammal may comprise:

- attaching an electronic device to the mammal, wherein the device comprises:
- at least two electrodes configured to detect physiological signals from the mammal,
- at least one measuring instrument configured to detect secondary signals, and
- at least two electrode traces connected to the electrodes and a rigid housing; and,
- comparing the physiological signals to the secondary signals to identify an artifact.

In certain embodiments, identification of an artifact comprises a comparison between the frequency spectrum of the physiological signals and the frequency spectrum of the secondary signals. In embodiments, the secondary signals comprise motion signals that may be used to derive the activity and position of the mammal. In certain embodiments, the secondary signals are collected in three axes. In some embodiments, a tertiary signal may also be collected. In certain embodiments, the secondary signals comprise information about the connection between the electronic device and the mammal. In some embodiments, the secondary signals may be used to detect when the mammal is sleeping.

In some embodiments, a method of removing and replacing portions of a modular physiological monitoring device may comprise

- applying the device of claim **1** to a mammal for a period of time greater than 7 days and collecting physiological data;
- using the device of claim **1** to detect a first set of physiological signals;
- removing the device of claim **1** from the surface of the mammal;
- removing a first component from the device of claim **1**; and,
- incorporating the first component into a second physiological monitoring device, the second physiological monitoring device configured to detect a second set of physiological signals.

In some embodiments, the first component is electrically connected to other device components without the use of a permanent connection. In some embodiments, the device may further comprise spring connections. In certain embodiments, the first component may be preserved for a second use by a rigid housing to prevent damage. In particular embodiments, the first component is secured within a device by a mechanism that is capable of re-securing a second component once the first component is removed.

These and other aspects and embodiments of the invention are described in greater detail below, with reference to the drawing figures.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1**A and **1**B are perspective and exploded views, respectively, of a physiological monitoring device, according to one embodiment;

FIGS. **2**A and **2**B are top perspective and bottom perspective views, respectively, of a printed circuit board assembly of the physiological monitoring device;

FIGS. **3**A-E are perspective and exploded views of a flexible body and gasket of the physiological monitoring device;

FIG. **4** is an exploded view of a rigid housing of the physiological monitoring device;

FIG. **5**A-B is a perspective view of a battery holder of the physiological monitoring device;

FIGS. **6**A and **6**B are cross sectional views of the physiological monitoring device;

FIG. **7** is an exploded view of the physiological monitoring device including a number of optional items, according to one embodiment;

FIGS. **8**A and **8**B are perspective views of two people wearing the physiological monitoring device, illustrating how the device bends to conform to body movement and position; and

FIGS. **9**A-**9**F illustrate various steps for applying the physiological monitor to a patient's body, according to one embodiment.

DETAILED DESCRIPTION

The following description is directed to a number of various embodiments. The described embodiments, however, may be implemented and/or varied in many different ways without departing from the scope of the invention. For example, the described embodiments may be implemented in any suitable device, apparatus, or system to monitor any of a number of physiological parameters. For example, the following discussion focuses primarily on long-term, patch-based cardiac rhythm monitoring devices. In one alternative embodiment, a physiological monitoring device may be used, for example, for pulse oximetry and diagnosis of obstructive sleep apnea. In various alternative embodiments, one size of physiological monitor may be used for adult patients and another size may be used for pediatric patients. The method of using a physiological monitoring device may also vary. In some cases, a device may be worn for one week or less, while in other cases, a device may be worn for at least seven days and/or for more than seven days, for example between fourteen days and twenty-one days or even longer. Many other alternative embodiments and applications of the described technology are possible. Thus, the following description is provided for exemplary purposes only. Throughout the specification, reference may be made to the term "conformal." It will be understood by one of skill in the art that the term "conformal" as used herein refers to a relationship between surfaces or structures where a first surface or structure fully adapts to the contours of a second surface or structure.

Referring to FIGS. **1**A and **1**B, perspective and exploded views of one embodiment of a physiological monitoring device **100** are provided. As seen in FIG. **1**A, physiological monitoring device **100** may include a flexible body **110** coupled with a watertight, rigid housing **115**. Flexible body **110** (which may be referred to as "flexible substrate" or "flexible construct") typically includes two wings **130**, **131**, which extend laterally from rigid housing **115**, and two flexible electrode traces **311**, **312**, each of which is embedded in one of wings **130**, **131**. Each electrode trace **311**, **312** is coupled, on the bottom surface of flexible body **110**, with a flexible electrode (not visible in FIG. **1**A). The electrodes are configured to sense heart rhythm signals from a patient to which monitoring device **100** is attached. Electrode traces **311**, **312** then transmit those signals to electronics (not visible in FIG. **1**A) housed in rigid housing **115**. Rigid housing **115** also typically contains a power source, such as one or more batteries.

As will be explained in further detail below, the combination of a highly flexible body **110**, including flexible electrodes and electrode traces **311**, **312**, with a very rigid housing **115** may provide a number of advantages. For example, flexible body **110** includes a configuration and various features that facilitate comfortable wearing of device **100** by a patient for fourteen (14) days or more without removal. Rigid housing **115**, which typically does not adhere to the patient in the embodiments described herein, includes features that lend to the comfort of device **100**. Rigid housing **115** also protects the electronics and power source contained in housing **120**, enhances the ability of a patient to provide an input related to a perceived cardiac event, and allows for simple manufacturing and reusability of at least some of the contents of housing **115**. These and other features of physiological monitoring device **100** are described in greater detail below.

Referring now to FIG. **1**B, a partially exploded view of physiological monitoring device **100** illustrates component parts that make up, and that are contained within, rigid housing **115** in greater detail. In this embodiment, rigid housing **115** includes an upper housing member **140**, which detachably couples with a lower housing member **145**. Sandwiched between upper housing member **140** and lower housing member **145** are an upper gasket **370**, and a lower gasket **360** (not visible on FIG. **1**B but just below upper gasket **370**). Gaskets **370**, **360** help make rigid housing member **115** watertight when assembled. A number of components of monitoring device **100** may be housed between upper housing member **140** and lower housing member **145**. For example, in one embodiment, housing **115** may contain a portion of flexible body **110**, a printed circuit board assembly (PCBA) **120**, a battery holder **150**, and two batteries **160**. Printed circuit board assembly **120** is positioned within housing **115** to contact electrode traces **311**, **312** and batteries **160**. In various embodiments, one or more additional components may be contained within or attached to rigid housing **115**. Some of these optional components are described further below, in reference to additional drawing figures.

Battery holder **150**, according to various alternative embodiments, may hold two batteries (as in the illustrated embodiment), one battery, or more than two batteries. In other alternative embodiments, other power sources may be used. In the embodiment shown, battery holder **150** includes

multiple retain tabs **153** for holding batteries **160** in holder **150**. Additionally, battery holder **150** includes multiple feet **152** to establish correct spacing of batteries **160** from the surface of PCBA **120** and ensure proper contact with spring fingers **235** and **236**. Spring fingers **235** and **236** are used in this embodiment rather than soldering batteries **160** to PCBA **120**. Although soldering may be used in alternative embodiments, one advantage of spring fingers **235** and **236** is that they allow batteries **160** to be removed from PCBA **120** and holder **150** without damaging either of those components, thus allowing for multiple reuses of both. Eliminating solder connections also simplifies and speeds up assembly and disassembly of monitoring device **100**.

In some embodiments, upper housing member **140** may act as a patient event trigger. When a patient is wearing physiological monitoring device **100** for cardiac rhythm monitoring, it is typically advantageous for the patient to be able to register with device **100** (i.e., log into the device's memory) any cardiac events perceived by the patient. If the patient feels what he/she believes to be an episode of heart arrhythmia, for example, the patient may somehow trigger device **100** and thus provide a record of the perceived event. At some later time, the patient's recorded perceived event could be compared with the patient's actual heart rhythm, recorded by device **100**, and this may help determine whether the patient's perceived events correlate with actual cardiac events. One problem with patient event triggers in currently available wearable cardiac rhythm monitoring devices, however, is that a small trigger may be hard to find and/or activate, especially since the monitoring device is typically worn under clothing. Additionally, pressing a trigger button may affect the electronics and/or the electrodes on the device in such a way that the recorded heart rhythm signal at that moment is altered simply by the motion caused to the device by the patient triggering. For example, pressing a trigger may jar one or both of the electrodes in such a way that the recorded heart rhythm signal at that moment appears like an arrhythmia, even if no actual arrhythmia event occurred. Additionally, there is a chance that the trigger may be inadvertently activated, for instance while sleeping or laying on the monitoring device.

In the embodiment shown in FIGS. **1**A and **1**B, however, rigid housing **115** is sufficiently rigid, and flexible body **110** is sufficiently flexible, that motion applied to housing **115** by a patient may rarely or ever cause an aberrant signal to be sensed by the electrodes. In this embodiment, the central portion of upper housing member **140** is slightly concave and, when pressed by a patient who is wearing device **100**, this central portion depresses slightly to trigger a trigger input on PCBA **120**. Because the entire upper surface of rigid housing **115** acts as the patient event trigger, combined with the fact that it is slightly concave, it will generally be quite easy for a patient to find and push down the trigger, even under clothing. Additionally, the concave nature of the button allows it to be recessed which protects it from inadvertent activations. Thus, the present embodiment may alleviate some of the problems encountered with patient event triggers on currently available heart rhythm monitors. These and other aspects of the features shown in FIGS. **1**A and **1**B will be described in further detail below.

Referring now to FIGS. **2**A and **2**B, printed circuit board assembly **120** (or "PCBA") may include a top surface **220**, a bottom surface **230**, a patient trigger input **210** and spring contacts **235**, **236**, and **237**. Printed circuit board assembly **120** may be used to mechanically support and electrically connect electronic components using conductive pathways, tracks or electrode traces **311**, **312**. Furthermore, because of the sensitive nature of PCBA **120** and the requirement to mechanically interface with rigid body **115**, it is beneficial to have PCBA **120** be substantially rigid enough to prevent unwanted deflections which may introduce noise or artifact into the ECG signal. This is especially possible during patient trigger activations when a force is transmitted through rigid body **115** and into PCBA **120**. One way to ensure rigidity of the PCBA is to ensure that the thickness of the PCBA is relatively above a certain value. For example, a thickness of at least about 0.08 cm is desirable and, more preferably, a thickness of at least about 0.17 cm is desirable. In this application, PCBA **120** may also be referred to as, or substituted with, a printed circuit board (PCB), printed wiring board (PWB), etched wiring board, or printed circuit assembly (PCA). In some embodiments, a wire wrap or point-to-point construction may be used in addition to, or in place of, PCBA **120**. PCBA **120** may include analog circuits and digital circuits.

Patient trigger input **210** may be configured to relay a signal from a patient trigger, such as upper housing member **140** described above, to PCBA **120**. For example, patient trigger input **210** may be a PCB switch or button that is responsive to pressure from the patient trigger (i.e., the upper surface of upper housing portion **140**). In various embodiments, patient trigger input **210** may be a surface mounted switch, a tactile switch, an LED illuminated tactile switch, or the like. In some embodiments, patient trigger input **210** may also activate an indicator, such as an LED.

One important challenge in collecting heart rhythm signals from a human or animal subject with a small, two-electrode physiological monitoring device such as device **100** described herein, is that having only two electrodes can sometimes provide a limited perspective when trying to discriminate between artifact and clinically significant signals. For example, when a left-handed patient brushes her teeth while wearing a small, two-electrode physiological monitoring device on her left chest, the tooth brushing may often introduce motion artifact that causes a recorded signal to appear very similar to Ventricular Tachycardia, a serious heart arrhythmia. Adding additional leads (and, hence, vectors) is the traditional approach toward mitigating this concern, but this is typically done by adding extra wires adhered to the patient's chest in various locations, such as with a Holter monitor. This approach is not consistent with a small, wearable, long term monitor such as physiological monitoring device **100**.

An alternate approach to the problem described above is to provide one or more additional data channels to aid signal discrimination. In some embodiments, for example, device **100** may include a data channel for detecting patch motion. In certain embodiments, an accelerometer may provide patch motion by simply analyzing the change in magnitude of a single axis measurement, or alternatively of the combination of all three axes. The accelerometer may record device motion at a sufficient sampling rate to allow algorithmic comparison of its frequency spectrum with that of the recorded ECG signal. If there is a match between the motion and recorded signal, it is clear that the device recording in that time period is not from a clinical (e.g., cardiac) source, and thus that portion of the signal can be confidently marked as artifact. This technique may be particularly useful in the tooth brushing motion example aforementioned, where the rapid frequency of motion as well as the high amplitude artifact is similar to the heart rate and morphology, respectively, of a potentially life-threatening arrhythmia like Ventricular Tachycardia.

In some embodiments, using the magnitude of all three axes for such an analysis would smooth out any sudden changes in values due to a shift in position rather than a change in activity. In other embodiments, there may be some advantage in using a specific axis of measurement such as along the longitudinal axis of the body to focus on a specific type of artifact introduced by upward and downward movements associated with walking or running. In a similar vein, the use of a gyroscope in conjunction with the accelerometer may provide further resolution as to the nature of the motion experienced. While whole body movements may be sufficiently analyzed with an accelerometer on its own, specific motion of interest such as rotational motion due to arm movement is sufficiently complex that an accelerometer alone might not be able to distinguish.

In addition to detecting motion artifact, an accelerometer tuned to the dynamic range of human physical activities may provide activity levels of the patient during the recording, which can also enhance accuracy of algorithmic true arrhythmia detection. Given the single-lead limitation of device **100**, arrhythmias that require observation of less prominent waves (e.g. P-wave) in addition to rate changes such as Supraventricular Tachycardia pose challenges to both computerized algorithms as well as the trained human eye. This particular arrhythmia is also characterized by the sudden nature of its onset, which may be more confidently discriminated from a non-pathological Sinus Tachycardia if a sudden surge in the patient's activity level is detected at the same time as the increase in heart rate. Broadly speaking, the provision of activity information to clinical professionals may help them discriminate between exercise-induced arrhythmia versus not. As with motion artifact detection, a single-axis accelerometer measurement optimized to a particular orientation may aid in more specifically determining the activity type such as walking or running. This additional information may help explain symptoms more specifically and thereby affect the subsequent course of therapeutic action.

In certain embodiments, an accelerometer with 3 axes may confer advantages beyond what magnitude of motions can provide. When the subject is not rapidly moving, 3-dimensional accelerometer readings may approximate the tilt of PCBA **120**, and therefore body orientation relative to its original orientation. The original body orientation can be assumed to be in either an upright or supine position which is required for appropriate positioning and application of the device to the body. This information may aid in ruling out certain cardiac conditions that manifest as beat-to-beat morphology changes, such as cardiac alternans where periodic amplitude changes are observed, often in heart failure cases. Similar beat-to-beat morphology changes are observable in healthy subjects upon shift in body position due to the shift in heart position relative to the electrode vector, for example from an upright to a slouching position. By design, the single-channel device **100** does not have an alternate ECG channel to easily rule out potential pathological shifts in morphology, however, correlation with shifts in body orientation will help explain these normal changes and avoid unnecessary treatment due to false diagnosis.

In other embodiments, the accelerometer may also be used as a sleep indicator, based on body orientation and movement. When presenting clinical events (e.g., pauses), it is diagnostically helpful to be able to present information in a manner that clearly separates events that occurred during sleep from those during waking hours. In fact, certain algorithms such as for ECG-derived respiratory rate only make sense to run when the patient is in a relatively motionless state and therefore subtle signal modulation introduced by chest movement due to breathing is observable. Respiratory rate information is useful as one channel of information necessary to detect sleep apnea in certain patient populations.

In certain embodiments, the accelerometer may also be used to detect free-falls, such as fainting. With an accelerometer, device **100** may be able to mark fainting (syncope) and other free-fall events without relying on patient trigger. In order to allow timely detection of such critical events, yet considering the battery and memory limitations of a small, wearable device such as device **100**, acquisition of accelerometer readings may be done in bursts, where only interesting information such as a potential free fall is written to memory at a high sampling rate. An expansion of this event-trigger concept is to use specific tapping motions on device **100** as a patient trigger instead of or in conjunction with the button previously described. The use and detection of multiple types of tapping sequences may provide better resolution and accuracy into what exactly the patient was feeling, instead of relying on the patient to manually record their symptom and duration in a trigger log after the fact. An example of such added resolution is to indicate the severity of the symptom by the number of sequential taps.

Alternatively, in other embodiments, an optical sensors may be used to distinguish between device motion and patient body motion. Further, in additional embodiments, the device may not require a button or trigger.

Another optional data channel that may be added to physiological monitoring device **100** is a channel for detecting flex and/or bend of device **100**. In various embodiments, for example, device **100** may include a strain gauge, piezoelectric sensor or optical sensor to detect motion artifact in device **100** itself and thus help to distinguish between motion artifact and cardiac rhythm data. Yet another optional data channel for device **100** may be a channel for detecting heart rate. For example, a pulse oximeter, microphone or stethoscope may provide heart rate information. Redundant heart rate data may facilitate discrimination of ECG signals from artifact. This is particularly useful in cases where arrhythmia such as Supraventricular Tachycardia is interrupted by artifact, and decisions must be made whether the episode was actually multiple shorter episodes or one sustained episode. Another data channel may be included for detecting ambient electrical noise. For example, device **100** may include an antenna for picking up electromagnetic interference. Detection of electromagnetic interference may facilitate discrimination of electrical noise from real ECG signals. Any of the above-described data channels may be stored to support future noise discrimination or applied for immediate determination of clinical validity in real-time.

With reference now to FIGS. **3**A and **3**B, flexible body **110** is shown in greater detail. As illustrated in FIG. **3**A, flexible body **110** may include wings **130**, **131**, a thin border **133** (or "rim" or "edge") around at least part of each wing **130**, **131**, electrode traces **311**, **312**, and a hinge portion **132** (or "shoulder") at or near a junction of each wing **130**, **131** with rigid housing **115**. Also shown in FIG. **3**A is upper gasket **370**, which is not considered part of flexible body **110** for this description, but which facilitates attachment of flexible body **110** to rigid housing **115**.

Hinge portions **132** are relatively thin, even more flexible portions of flexible body **110**. They allow flexible body **110** to flex freely at the area where it is joined to rigid housing **115**. This enhances comfort, since when the patient moves, housing **115** can freely lift off of the patient's skin. Electrode traces **311**, **312** are also very thin and flexible, to allow for

patient movement without signal distortion. Borders **133** are portions of flexible body **110** that is thinner than immediately adjacent portions and that provide for a smooth transition from flexible body **110** to a patient's skin, thus preventing edge-lift and penetration of dirt or debris below flexible body **110**.

As shown in greater detail in FIG. **3**B, flexible body **110** may include multiple layers. As mentioned previously, upper gasket **370** and lower gasket **360** are not considered part of flexible body **110** for the purposes of this description but are shown for completeness of description. This distinction is for case of description only, however, and should not be interpreted to limit the scope of the claimed invention. Flexible body **110** may include a top substrate layer **300**, a bottom substrate layer **330**, an adhesive layer **340**, and flexible electrodes **350**. Top and bottom substrate layers **300**, **330** may be made of any suitable, flexible material, such as one or more flexible polymers. Suitable flexible polymers can include, but are not limited to, polyurethane, polyethylene, polyester, polypropylene, nylon, teflon and carbon impregnated vinyl. The material of substrate layers **300**, **330** may be selected based on desired characteristics. For example, the material of substrate layers **300**, **330** may be selected for flexibility, resilience, durability, breathability, moisture transpiration, adhesion and/or the like. In one embodiment, for example, top substrate layer **300** may be made of polyurethane, and bottom substrate layer **330** may be made of polyethylene or alternatively polyester. In other embodiments, substrate layers **300**, **330** may be made of the same material. In yet another embodiment, substrate layer **330** may contain a plurality of perforations in the area over adhesive layer **340** to provide for even more breathability and moisture transpiration. In various embodiments, physiological monitoring device **100** may be worn continuously by a patient for as many as 14-21 days or more, without removal during the time of wear and with device **100** being worn during showering, exercising and the like. Thus, the material(s) used and the thickness and configuration of substrate layers **300**, **330** may be essential to the function of physiological monitoring device **100**. In some embodiments, the material of substrate layers **300**, **330** acts as an electric static discharge (ESD) barrier to prevent arcing.

Typically, top and bottom substrate layers **300**, **330** are attached to one another via adhesive placed on one or both layers **300**, **330**. For example, the adhesive or bonding substance between substrate layers **300**, **330** may be an acrylic-based, rubber-based, or silicone-based adhesive. In other alternative embodiments, flexible body **110** may include more than two layers of flexible material.

In addition to the choice of material(s), the dimensions—thickness, length and width—of substrate layers **300**, **330** may be selected based on desired characteristics of flexible body **110**. For example, in various embodiments, the thickness of substrate layers **300**, **330** may be selected to give flexible body **110** an overall thickness of between about 0.1 mm to about 1.0 mm. According to various embodiments, flexible body **110** may also have a length of between about 7 cm and 15 cm and a width of about 3 cm and about 6 cm. Generally, flexible body **110** will have a length sufficient to provide a necessary amount of separation between electrodes **350**. For example, a distance from the center of one electrode **350** to the center of the other electrode **350** should be at least about 6.0 cm and more preferably at least about 8.5 cm. This separation distance may vary, depending on the application. In some embodiments, substrate layers **300**, **330** may all have the same thickness. Alternatively, the two substrate layers **300**, **330** may have different thicknesses.

As mentioned above, hinge portions **132** allow the rigid body **115** to lift away from the patient while flexible body **110** remains adhered to the skin. The functionality of hinge portions **132** is critical in allowing the device to remain adhered to the patient throughout various activities that may stretch and compress the skin. Furthermore, hinge portions **132** allow for significantly improved comfort while wearing the device. Generally, hinge portions **132** will be sufficiently wide enough to provide adequate lift of rigid body **115** without creating too large of a peel force on flexible body **110**. For example, in various embodiments, the width of hinge portion **132** should be at least about 0.25 cm and more preferably at least about 0.75 cm.

Additionally, the shape or footprint of flexible body **110** may be selected based on desired characteristics. As seen in FIG. **3**A, wings **130**, **131** and borders **133** may have rounded edges that give flexible body **110** an overall "peanut" shape. However, wings **130**, **131** can be formed in any number of different shapes such as rectangles, ovals, loops, or strips. In the embodiment shown in FIGS. **3**A and **3**B, the footprint top substrate layer **300** is larger than the footprint of bottom substrate layer **330**, with the extension of top substrate layer **300** forming borders **133**. Thus, borders **133** are made of the same polyurethane material that top layer **300** is made of. Borders **133** are thinner than an adjacent portion of each wing **130**, **131**, since they includes only top layer **300**. The thinner, highly compliant rim **133** will likely enhance adherence of physiologic monitoring device **100** to a patient, as it provides a transition from an adjacent, slightly thicker portion of wings **130**, **131** to the patient's skin and thus helps prevent the edge of device **110** from peeling up off the skin. Border **133** may also help prevent the collection of dirt and other debris under flexible body **110**, which may help promote adherence to the skin and also enhance the aesthetics of device **110**. In alternative embodiments, the footprint of substrate layers **300**, **330** may be the same, thus eliminating borders **133**.

While the illustrated embodiments of FIGS. **1**A-**3**B include only two wings **130**, **131**, which extend from rigid housing **115** in approximately opposite directions (i.e., at a 180-degree angle relative to each other), other configurations are possible in alternative embodiments. For example, in some embodiments, wings **130**, **131** may be arranged in an asymmetrical orientation relative to one another and/or one or more additional wings may be included. As long as sufficient electrode spacing is provided to permit physiological signal monitoring, and as long as wings **130**, **131** are configured to provide extended attachment to the skin, any suitable configuration and number of wings **130**, **131** and electrode traces **311**, **312** may be used. The embodiments described above have proven to be advantageous for adherence, patient comfort and accuracy of collected heart rhythm data, but in alternative embodiments it may be possible to implement alternative configurations.

Adhesive layer **340** is an adhesive that is applied to two portions of the bottom surface of bottom substrate layer **330**, each portion corresponding to one of wings **130**, **131**. Adhesive layer **340** thus does not extend along the portion of bottom substrate layer **330** upon which rigid housing **115** is mounted. Adhesive layer **340** may be made of any suitable adhesive, although certain adhesives have been found to be advantageous for providing long term adhesion to patient skin with relative comfort and lack of skin irritation. For example, in one embodiment, adhesive layer **340** is a hydrocolloid adhesive. In another embodiment, the adhesive layer **340** is comprised of a hydrocolloid adhesive that

contains naturally-derived or synthetic absorbent materials which take up moisture from the skin during perspiration.

Each of the two portions of adhesive layer **340** includes a hole, into which one of electrodes **350** fits. Electrodes **350** made of flexible material to further provide for overall conformability of flexible body **110**. In one embodiment, for example, flexible electrodes **350** may be made of a hydrogel **350**. Electrodes **350** generally provide conformal, non-irritating contact with the skin to provide enhanced electrical connection with the skin and reduce motion artifact. In some embodiments, hydrogel electrodes **350** may be punched into adhesive layer **340**, thus forming the holes and filling them with hydrogel electrodes **350**. In one alternative embodiment, electrodes **350** and adhesive **340** may be replaced with an adhesive layer made of a conductive material, such that the entire adhesive layer on the underside of each wing **130**, **131** acts as an electrode. Such an adhesive layer may include a hybrid adhesive/conductive substance or adhesive substance mixed with conductive elements or particles. For example, in one embodiment, such an adhesive layer may be a hybrid of a hydrogel and a hydrocolloid adhesive.

As discussed above, in some embodiments, adhesive layer **340** may cover a portion of the underside of lower substrate layer **330**, such that at least a portion of the bottom side of flexible body **110** does not include adhesive layer **340**. As seen in FIG. **3**A, hinges **132** may be formed in the flexible body **110** as portions of each wing **130**, **131** on which adhesive layer **340** is not applied. Hinge portions **132** are generally located at or near the junction of flexible body **110** with rigid housing **115**, and thus provide for flexing of device **100** to accommodate patient movement. In some embodiments, hinge portions **132** may have a width that is less than that of adjacent portions of wings **130**, **131**, thus giving device **100** its "peanut" shape mentioned above. As shown in FIG. **8**, as a subject moves, device **100** flexes along with patient movement. Device flexion may be severe and is likely to occur many times during long term monitoring. Hinge portions **132** may allow for dynamic conformability to the subject, while the rigidity of rigid housing **115** may allow housing **115** to pop up off the patient's skin during device flexion, thus preventing peeling of the device **100** off of the skin at its edge.

Flexible body **110** further includes two electrode traces **311**, **312** sandwiched between upper substrate layer **300** and lower substrate layer **330**. Each electrode trace **311**, **312** may include an electrode interface portion **310** and an electrocardiogram circuit interface portion **313**. As illustrated in FIGS. **3**C and **3**D, ECG circuit interface portions **313** are in physical contact with spring fingers **237** and provide electrical communication with PCBA **120** when device **100** or zoomed-in device portion **101** is assembled. Electrode interface portions **310** contact hydrogel electrodes **350**. Thus, electrode traces **311**, **312** transmit cardiac rhythm signals (and/or other physiological data in various embodiments) from electrodes **350** to PCBA **120**.

The material and thickness of electrode traces **311**, **312** are important for providing a desired combination of flexibility, durability and signal transmission. For example, in one embodiment, electrode traces **311**, **312** may include a combination of silver (Ag) and silver chloride (AgCl). The silver and silver chloride may be disposed in layers. For example, one embodiment of electrode traces **311**, **312** may include a top layer of silver, a middle layer of carbon impregnated vinyl, and a bottom (patient-facing) layer of silver chloride. In another embodiment, both top and bottom layers of electrode traces **311**, **312** may be made of silver chloride. In one embodiment, the top and bottom layers may be applied to the middle layer in the form of silver ink and silver chloride ink, respectively. In an alternative embodiment, each electrode trace may include only two layers, such as a top layer of silver and a bottom layer of silver chloride. In various embodiments, the material of a bottom layer of each electrode trace **311**, **312**, such as AgCl, may be selected to match the chemistry of the hydrogel electrodes **350** and create a half-cell with the body of the subject.

The thickness of the electrode traces **311**, **312** may be selected to optimize any of a number of desirable properties. For example, in some embodiments, at least one of the layers of electrode traces **311**, **312** can be of a sufficient thickness to minimize or slow depletion of the material from an anode/cathode effect over time. Additionally, the thickness may be selected for a desired flexibility, durability and/or signal transmission quality. Flexible electrode traces **311**, **312** generally may help provide conformal contact with the subject's skin and may help prevent electrodes **350** from peeling or lifting off of the skin, thereby providing strong motion artifact rejection and better signal quality by minimizing transfer of stress to electrodes **350**.

As mentioned above, in some embodiments, top gasket **370** and bottom gasket **360** may be attached upper substrate **300** and lower substrate **330** of flexible body **110**. Gaskets **360**, **370** may be made of any suitable material, such as urethane, which provides a water tight seal between the upper housing member **140** and lower housing member **145** of rigid housing **115**. In one embodiment, top gasket **370** and/or bottom gasket **360** may include an adhesive surface. FIG. **3**E depicts yet another embodiment where top gasket **370** includes tabs **371** that protrude away from the profile of top housing **140** while still being adhered to upper substrate **300**. The tabs **371** cover a portion of electrode traces **311**, **312** and provide a strain relief for the traces at the point of highest stress where the flexible body meets the rigid housing.

With reference now to FIG. **4**, upper housing member **140** and lower housing member **145** of rigid housing **115** are shown in greater detail. Upper and lower housing members **140**, **145** may be configured, when coupled together with gaskets **360**, **370** in between, to form a watertight enclosure for containing PCBA **120**, battery holder **150**, batteries **160** and any other components contained within rigid housing **115**. Housing members **140**, **145** may be made of any suitable material to protect internal components, such as water resistant plastic. In one embodiment, upper housing member **140** may include a rigid sidewall **440**, a light pipe **410** to transmit visual information from the LEDs on the PCBA through the housing member, a slightly flexible top surface **420**, and an inner trigger member **430** extending inward from top surface **420**. Top surface **420** is configured to be depressed by a patient when the patient perceives what he or she believes to be an arrhythmia or other cardiac event. When depressed, top surface **420** depresses inner trigger member **430**, which contacts and activates trigger input **210** of PCBA **120**. Additionally, as discussed previously, top surface **420** may have a concave shape (concavity facing the inside of housing **115**) to accommodate the shape of a finger. It is believed that the design of upper housing member **140** isolates activation of the trigger input **210** from electrodes **350**, thereby minimizing artifact in the data recording.

With continued reference to FIG. **4**, lower housing member **145** may be configured to detachably connect with upper housing member **140** in such a way that housing members **140**, **145** may be easily attached and detached for reusability of at least some of the component parts of monitoring device **100**. In some embodiments, a bottom surface **445** (patient

facing surface) of lower housing member **145** may include multiple dimples **450** (or "bumps," "protrusions" or the like), which will contact the patient's skin during use. Dimples **450** may allow for air flow between bottom surface **445** and the patient's skin, thus preventing a seal from forming between bottom surface **445** and the skin. It is believed that dimples **450** improve comfort and help prevent a perception in currently available devices in which the patient feels as if monitoring device **100** is falling off when it housing **115** lifts off the skin and breaks a seal with the skin. In yet another embodiment the bottom surface **445** of lower housing member **450** may include multiple divots (recesses instead of protrusions) to prevent a seal from forming.

Referring now to FIG. **5**A, battery holder **150** is shown in greater detail. Battery holder **150** may be made of plastic or other suitable material, is configured to be mounted to PCBA **120** and subsequently attached to rigid housing **115**, and is capable of holding two batteries **160** (FIG. **1**B). In alternative embodiments, battery holder **150** may be configured to hold one battery or more than two batteries. A plurality of protrusions **152** provide a stable platform for batteries **160** to be positioned a fixed distance above the surface of PCBA **120**, avoiding unwanted contact with sensitive electronic components yet providing for adequate compression of spring contacts **235** (FIG. **5**B). Protrusions **153** lock batteries **160** into position and resist the upward force on the batteries from spring contacts **235**. Battery holder **150** also positions batteries appropriately **160** to provide for adequate compression of spring contacts **236**. Use of battery holder **150** in conjunction with spring contacts **235** and **236** allows for batteries **160** to be electrically connected to PCBA **120** while still having additional electronic components between batteries **160** and PCBA **120** and maintain a very compact assembly. Battery holder **150** may include a flexible hook **510** which engages a corresponding rigid hook **440** of upper housing member **140**. Under normal assembly conditions the flexible hook **510** remains securely mated with rigid hook **440**. For disassembly, flexible hook **510** can be pushed and bent using an appropriate tool passed through top housing **140** causing it to disengage from rigid hook **440** and subsequently allow top housing **140** to be removed.

With reference now to FIGS. **6**A and **6**B, physiological monitoring device **100** is shown in side view cross-section. As shown in **6**A, physiological monitoring device **100** may include flexible body **110** coupled with rigid housing **115**. Flexible body **110** may include top substrate layer **300**, bottom substrate layer **330**, adhesive layer **340** and electrodes **350**. Electrode traces **311**, **312** are also typically part of flexible body **110** and are embedded between top substrate layer **300** and bottom substrate layer **330**, but they are not shown in FIG. **6**. Flexible body **110** forms two wings **130**, **131**, extending to either side of housing **115**, and a border **133** surrounding at least part of each wing **130**, **131**. Rigid housing **115** may include an upper housing member **140** coupled with a lower housing member **145** such that it sandwiches a portion of flexible body **110** in between and provides a watertight, sealed compartment for PCBA **120**. Upper housing member **140** may include inner trigger member **430**, and PCBA may include patient trigger member **210**. As discussed previously, lower housing member **145** may include multiple dimples **450** or divots to enhance the comfort of the monitoring device **100**.

It is desirable that PCBA **120** is sufficiently rigid to prevent bending and introducing unwanted artifact into the signal. In certain embodiments, an additional mechanism to reduce and prevent unwanted bending of PCBA **120** may be used. This mechanism is shown in FIG. **6**B. Support post **460** is integral to lower housing **145** and is positioned directly under patient trigger input **210**. During patient symptom triggering, upper housing member **140** is depressed, engaging inner trigger mechanism **430** and transmitting a force through patient trigger input **210** into PCBA **120**. The force is further transmitted through PCBA **120** and into support post **460** without creating a bending moment, thus avoiding unwanted artifact.

Referring to FIG. **7**, in some embodiments, physiological monitoring device **100** may include one or more additional, optional features. For example, in one embodiment, monitoring device **100** may include a removable liner **810**, a top label **820**, a device identifier **830** and a bottom label **840**. Liner **810** may be applied over a top surface of flexible member **110** to aid in the application of device **100** to the subject. As is described in further detail below, liner **810** may help support borders **133** of flexible body **110**, as well as wings **130**, **131**, during removal of one or more adhesive covers (not shown) that cover adhesive surface **340** before use. Liner **810** may be relative rigid and/or firm, to help support flexible body **110** during removal of adhesive covers. In various embodiments, for example, liner **810** may be made of cardboard, thick paper, plastic or the like. Liner **810** typically includes an adhesive on one side for adhering to the top surface of wings **130**, **131** of flexible body **110**.

Labels **820**, **840** may be any suitable labels and may include produce name(s), manufacturer name(s), logo(s), design(s) and/or the like. They may be removable or permanently attached upper housing member **140** and/or lower housing member **145**, although typically they will be permanently attached, to avoid unregulated reuse and/or resale of the device by an unregistered user. Device identifier **830** may be a barcode sticker, computer readable chip, RFID, or the like. Device identifier **830** may be permanently or removably attached to PCBA **120**, flexible body **110** or the like. In some embodiments, it may be beneficial to have device identifier **830** stay with PCBA **120**.

Referring now to FIGS. **8**A and **8**B, physiological monitoring device **100** generally includes hinge portions **132** at or near the juncture of each wing **130**, **131** with rigid housing **115**. Additionally, each wing **130**, **131** is typically adhered to the patient via adhesive layers **340**, while rigid body **115** is not adhered to the patient and is thus free to "float" (i.e., move up and down) over the patient's skin during movement and change of patient position. In other words, when the patient's chest contracts, rigid housing pops up or floats over the skin, thus minimizing stress on device **100**, enhancing comfort, and reducing the tendency of wings **130**, **131** to peel off of the skin. The advantage provided by the combination of the floating rigid body **115** and the adhered wings **130**, **131** is illustrated in FIGS. **8**A and **8**B. In FIG. **8**A, a patient is sleeping, and in FIG. **8**B, a patient is playing golf. In both examples, monitoring device **100** is squeezed together by the patient's body, causing rigid housing **115** to float above the skin as wings **130**, **131** move closer together. This advantage of a floating, non-attached portion of a physiological monitoring device is described in further detail in U.S. Pat. No. 8,560,046, which was previously incorporated by reference.

Referring now to FIGS. **9**A-**9**F, one embodiment of a method for applying physiological monitoring device **100** to the skin of a human subject is described. In this embodiment, before the first step shown in FIG. **9**A, the patient's skin may be prepared, typically by shaving a small portion of the skin on the left chest where device **100** will be placed and then

abrading and/or cleaning the shaved portion. As shown in FIG. **9**A, once the patient's skin is prepared, a first step of applying device **100** may include removing one or both of two adhesive covers **600** from adhesive layers **340** on the bottom surface of device **100**, thus exposing adhesive layers **340**. As illustrated in FIG. **9**B, the next step may be to apply device **100** to the skin, such that adhesive layer **340** adheres to the skin in a desired location. In some embodiments, one adhesive cover **600** may be removed, the uncovered adhesive layer **340** may be applied to the skin, and then the second adhesive cover **600** may be removed, and the second adhesive layer **340** may be applied to the skin. Alternatively, both adhesive covers **600** may be removed before applying device **100** to the skin. While adhesive covers **600** are being removed, liner **810** acts as a support for flexible body **110**, provides the physician or other user with something to hold onto, and prevents flexible body **110** and borders **133** of flexible body **110** from folding in on themselves, forming wrinkles, etc. As described above, liner **810** may be made of a relatively stiff, firm material to provide support for flexible body **110** during application of device **100** to the skin. Referring to FIG. **9**C, after device **100** has been applied to the skin, pressure may be applied to flexible body **110** to press it down onto the chest to help ensure adherence of device **100** to the skin.

In a next step, referring to FIG. **9**D, liner **810** is removed from (peeled off of) the top surface of flexible body **110**. As shown in FIG. **9**E, once liner **810** is removed, pressure may again be applied to flexible body **110** to help ensure it is adhered to the skin. Finally, as shown in FIG. **9**F, upper housing member **140** may be pressed to turn on physiological monitoring device **140**. This described method is only one embodiment. In alternative embodiments, one or more steps may be skipped and/or one or more additional steps may be added.

When a desired monitoring period has ended, such as about 14-21 days in some cases, a patient (or physician, nurse or the like) may remove physiological monitoring device **100** from the patient's skin, place device **100** in a prepaid mailing pouch, and mail device **100** to a data processing facility. At this facility, device **100** may be partially or completely disassembled, PCBA **120** may be removed, and stored physiological data, such as continuous heart rhythm information, may be downloaded from PCBA **120**. The data may then be analyzed by any suitable method and then provided to a physician in the form of a report. The physician may then discuss the report with the patient. PCBA **120** and/or other portions of device **100**, such as rigid housing **115**, may be reused in the manufacture of subsequent devices for the same or other patients. Because device **100** is built up as a combination of several removably coupled parts, various parts may be reused for the same embodiment or different embodiments of device **100**. For example, PCBA **120** may be used first in an adult cardiac rhythm monitor and then may be used a second time to construct a monitor for sleep apnea. The same PCBA **120** may additionally or alternatively be used with a differently sized flexible body **110** to construct a pediatric cardiac monitor. Thus, at least some of the component parts of device **100** may be interchangeable and reusable.

Advantageously, physiological monitoring device **100** may provide long term adhesion to the skin. The combination of the configuration of flexible and conformal body **110**, the watertight, low profile configuration of rigid housing **115**, and the interface between the two allows device **100** to compensate for stress caused as the skin of the subject stretches and bends. As a result, device **100** may be worn continuously, without removal, on a patient for as many as 14-21 days or more. In some cases, device **100** may be worn for greater or less time, but 14-21 days may often be a desirable amount of time for collecting heart rhythm data and/or other physiological signal data from a patient.

In various alternative embodiments, the shape of a particular physiological monitoring device may vary. The shape, footprint, perimeter or boundary of the device may be circular, an oval, triangular, a compound curve or the like, for example. In some embodiments, the compound curve may include one or more concave curves and one or more convex curves. The convex shapes may be separated by a concave portion. The concave portion may be between the convex portion on the rigid housing and the convex portion on the electrodes. In some embodiments, the concave portion may correspond at least partially with a hinge, hinge region or area of reduced thickness between the body and a wing.

While described in the context of a heart monitor, the device improvements described herein are not so limited. The improvements described in this application may be applied to any of a wide variety of physiological data monitoring, recording and/or transmitting devices. The improved adhesion design features may also be applied to devices useful in the electronically controlled and/or time released delivery of pharmacological agents or blood testing, such as glucose monitors or other blood testing devices. As such, the description, characteristics and functionality of the components described herein may be modified as needed to include the specific components of a particular application such as electronics, antenna, power supplies or charging connections, data ports or connections for down loading or off loading information from the device, adding or offloading fluids from the device, monitoring or sensing elements such as electrodes, probes or sensors or any other component or components needed in the device specific function. In addition or alternatively, devices described herein may be used to detect, record, or transmit signals or information related to signals generated by a body including but not limited to one or more of ECG, EEG and/or EMG.

While the above embodiments disclose the invention with respect to a data channel for collecting a single physiological signal, it is contemplated that additional data channels can be include to collect additional data, for example, device motion, device flex or bed, heart rate and/or ambient electrical noise.

Various embodiments of a physiological monitoring device and methods for using it have been disclosed above. These various embodiments may be used alone or in combination, and various changes to individual features of the embodiments may be altered, without departing from the scope of the invention. For example, the order of various method steps may in some instances be changed, and/or one or more optional features may be added to or eliminated from a described device. Therefore, the description of the embodiments provided above should not be interpreted as unduly limiting the scope of the invention as it is set forth in the claims.

Various modifications to the implementations described in this disclosure may be made, and the generic principles defined herein may be applied to other implementations without departing from the spirit or scope of this disclosure. Thus, the claims are not intended to be limited to the implementations shown herein, but are to be accorded the widest scope consistent with this disclosure, the principles and the novel features disclosed herein.

Certain features that are described in this specification in the context of separate embodiments also can be implemented in combination in a single embodiment. Conversely, various features that are described in the context of a single embodiment also can be implemented in multiple embodiments separately or in any suitable subcombination. Moreover, although features may be described above as acting in certain combinations and even initially claimed as such, one or more features from a claimed combination can in some cases be excised from the combination, and the claimed combination may be directed to a subcombination or variation of a subcombination.

Similarly, while operations are depicted in the drawings in a particular order, such operations need not be performed in the particular order shown or in sequential order, or that all illustrated operations be performed, to achieve desirable results. Further, the drawings may schematically depict one more example processes in the form of a flow diagram. However, other operations that are not depicted can be incorporated in the example processes that are schematically illustrated. For example, one or more additional operations can be performed before, after, simultaneously, or between any of the illustrated operations. Moreover, the separation of various system components in the embodiments described above should not be interpreted as requiring such separation in all embodiments. Additionally, other embodiments are within the scope of the following claims. In some cases, the actions recited in the claims can be performed in a different order and still achieve desirable results.

What is claimed is:

1. A physiological monitoring device configured to monitor cardiac rhythm data of a patient, the physiological monitoring device comprising:

a spring contact configured to electrically couple a battery to a circuit board assembly housed within a first housing portion;

a flexible substrate coupled to a second housing portion, wherein the flexible substrate comprises a first layer and a second layer, and wherein the first layer extends beyond the second layer creating an edge to the flexible substrate that is thinner than an inner portion of the flexible substrate;

an electrode coupled to the flexible substrate and configured to detect physiological signals of the patient to obtain the cardiac rhythm data;

a support post configured such that force from interaction with a trigger is transmitted to the support post; and

a flexible electrode trace coupled to the flexible substrate and configured to electrically couple the electrode to the circuit board assembly, wherein at least a portion of the flexible electrode trace is in electrical contact with a second spring contact, and wherein the second spring contact is further configured to electrically couple the flexible electrode trace to the circuit board assembly.

2. The physiological monitoring device of claim **1**, wherein the force is transmitted through the circuit board assembly.

3. The physiological monitoring device of claim **1**, wherein the first housing portion detachably couples to the second housing portion.

4. The physiological monitoring device of claim **1**, wherein the electrode is embedded within a portion of the flexible substrate.

5. The physiological monitoring device of claim **1**, wherein the spring contact is in physical contact with an electrocardiogram circuit interface.

6. The physiological monitoring device of claim **1**, wherein the support post is positioned between the circuit board assembly and a housing portion.

7. The physiological monitoring device of claim **6**, wherein the housing portion comprises the second housing portion.

8. The physiological monitoring device of claim **1**, wherein the support post is positioned below the trigger.

9. The physiological monitoring device of claim **1**, wherein the support post is integral with a housing portion.

10. The physiological monitoring device of claim **1**, wherein the force is transmitted to the support post without creating a bending moment.

11. The physiological monitoring device of claim **1**, wherein the first housing portion comprises a rigid housing configured to prevent deformation of the circuit board assembly in response to movement of the patient.

12. The physiological monitoring device of claim **1**, wherein the flexible substrate forms an electrode-supporting section.

13. The physiological monitoring device of claim **1**, further comprising a gasket configured to make a housing, formed from at least the first housing portion and the second housing portion, watertight.

14. The physiological monitoring device of claim **1**, wherein the flexible electrode trace is sandwiched between a first layer and a second layer of the flexible substrate.

15. The physiological monitoring device of claim **1**, wherein the circuit board assembly is substantially rigid.

16. The physiological monitoring device of claim **1**, further comprising the trigger, wherein the trigger is configured to cause a signal to be relayed to the circuit board assembly in response to user interaction with the trigger.

17. The physiological monitoring device of claim **16**, wherein the trigger comprises a button.

18. The physiological monitoring device of claim **1**, further comprising an adhesive layer located on at least a portion of the flexible substrate and configured to adhere to skin of the patient.

19. The physiological monitoring device of claim **18**, wherein the adhesive layer is configured to adhere to the skin of the patient for at least 7 days enabling the physiological monitoring device to monitor the cardiac rhythm data of the patient for at least 7 days.

20. The physiological monitoring device of claim **1**, further comprising an LED indicator configured to indicate activation.

21. The physiological monitoring device of claim **1**, further comprising a second electrode embedded within a second portion of the flexible substrate.

22. The physiological monitoring device of claim **1**, wherein the flexible substrate comprises a border portion that is thinner than an interior portion of the flexible substrate, and wherein the border portion is configured to reduce edge-lift of the flexible substrate when affixed to the patient.

23. The physiological monitoring device of claim **1**, wherein the first layer is in contact with the second layer.

24. The physiological monitoring device of claim **1**, wherein the spring contact comprises a spring finger.

25. The physiological monitoring device of claim **1**, wherein the support post is further configured to remain rigid during depression of the trigger.

* * * * *

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Kumar et al.

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(54) **DEVICE FEATURES AND DESIGN ELEMENTS FOR LONG-TERM ADHESION**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(58) **Field of Classification Search**
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(Continued)

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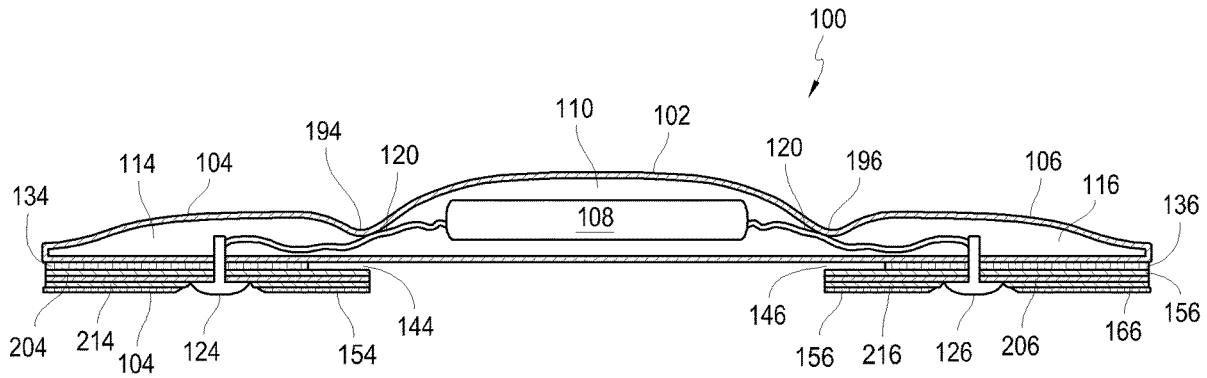
(57) **ABSTRACT**

An electronic device for long-term adhesion to a mammal includes a housing with an electronic component. The electronic device may include a first wing and a second wing, each being integrally formed with the housing. An electrode is positioned on a bottom surface of each of the wings, the electrodes electrically connected to the electronic component. An adhesive layer is provided for adhesion to a surface of the mammal. The adhesive layer may cover a portion of the bottom surfaces of the wings but generally does not cover the electrode or a bottom surface of the housing. A method of applying an electronic device to a mammal includes removing first and second adhesive covers
(Continued)



from first and second wings of the electronic device to expose an electrode and an adhesive coated on a bottom surface of each wing.

13 Claims, 11 Drawing Sheets

Related U.S. Application Data

continuation of application No. 16/723,208, filed on Dec. 20, 2019, now Pat. No. 11,141,091, which is a continuation of application No. 16/138,819, filed on Sep. 21, 2018, now Pat. No. 10,517,500, which is a continuation of application No. 15/005,854, filed on Jan. 25, 2016, now Pat. No. 10,405,799, which is a continuation of application No. 13/890,144, filed on May 8, 2013, now Pat. No. 9,241,649, which is a continuation of application No. 13/563,546, filed on Jul. 31, 2012, now Pat. No. 8,538,503, which is a continuation of application No. 13/106,750, filed on May 12, 2011, now Pat. No. 8,560,046.

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See application file for complete search history.

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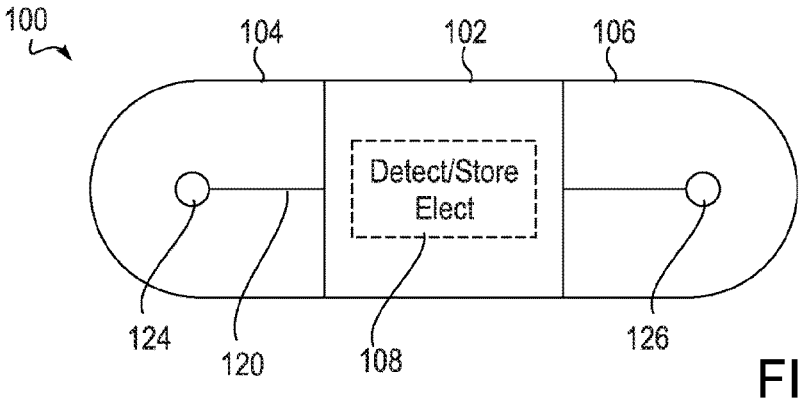
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FIG. 1

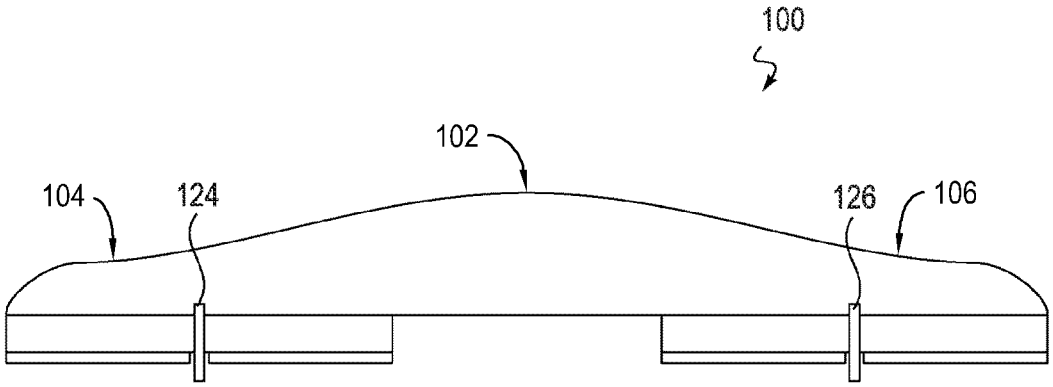
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FIG. 1A

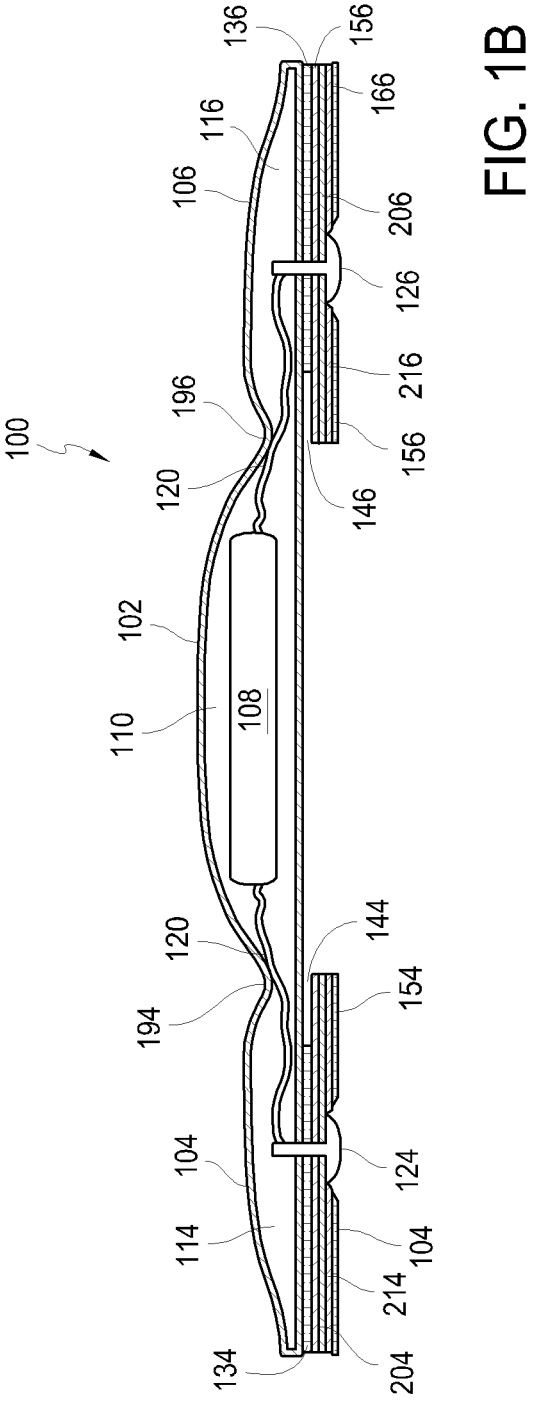
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FIG. 1B

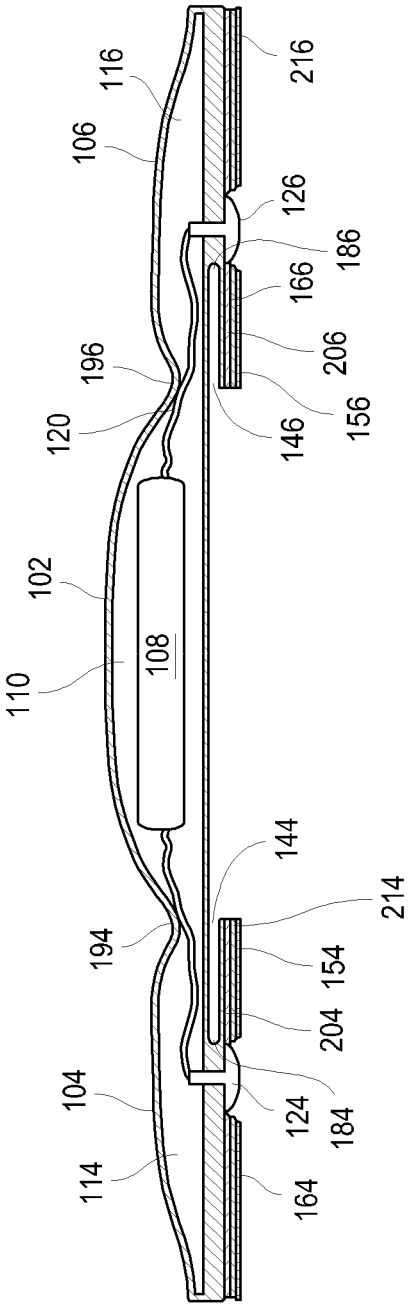
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FIG. 1C

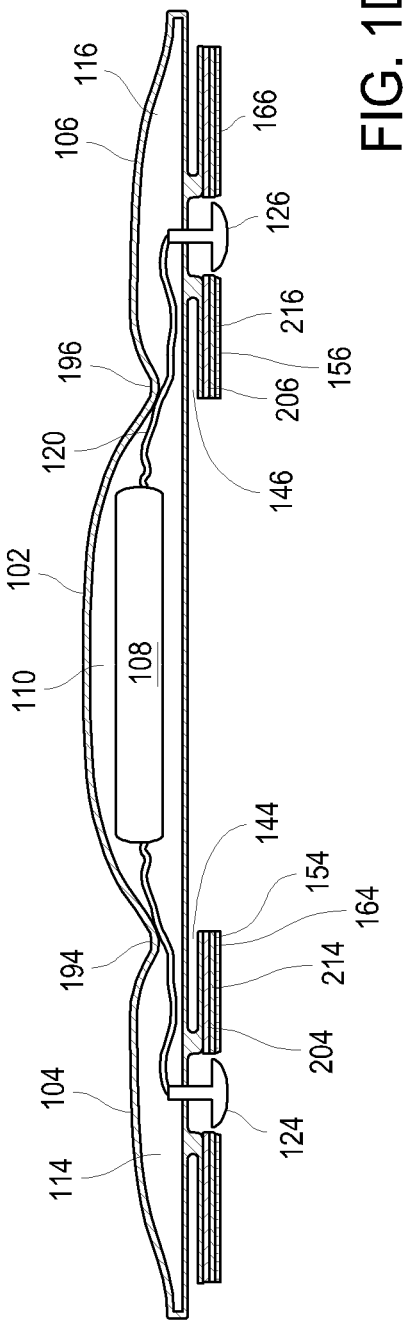
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FIG. 1D

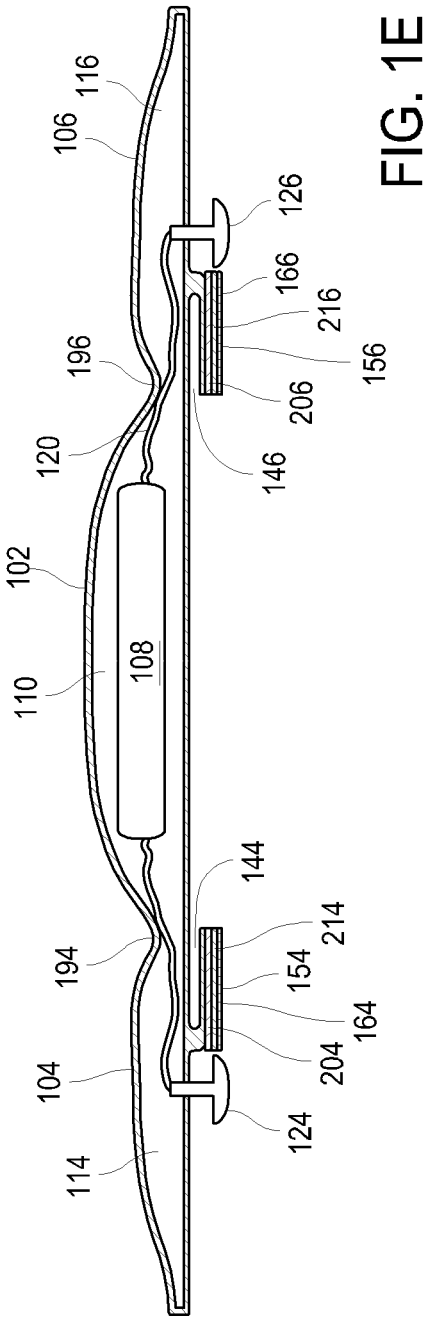
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FIG. 1E

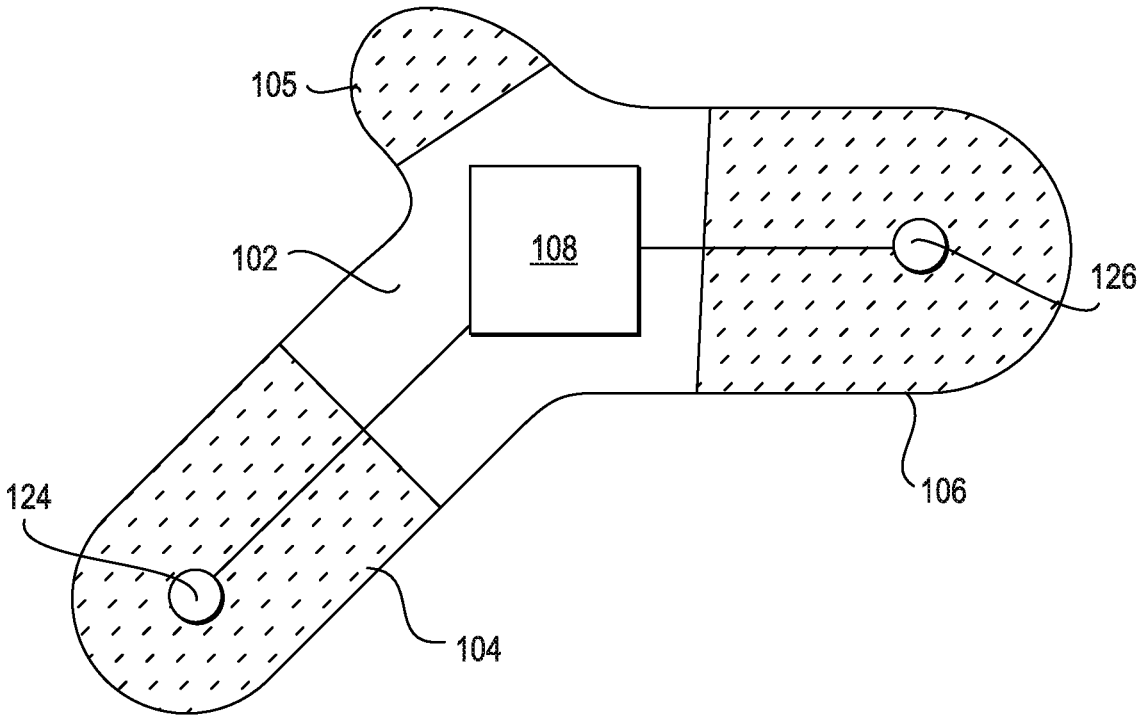


FIG. 1F

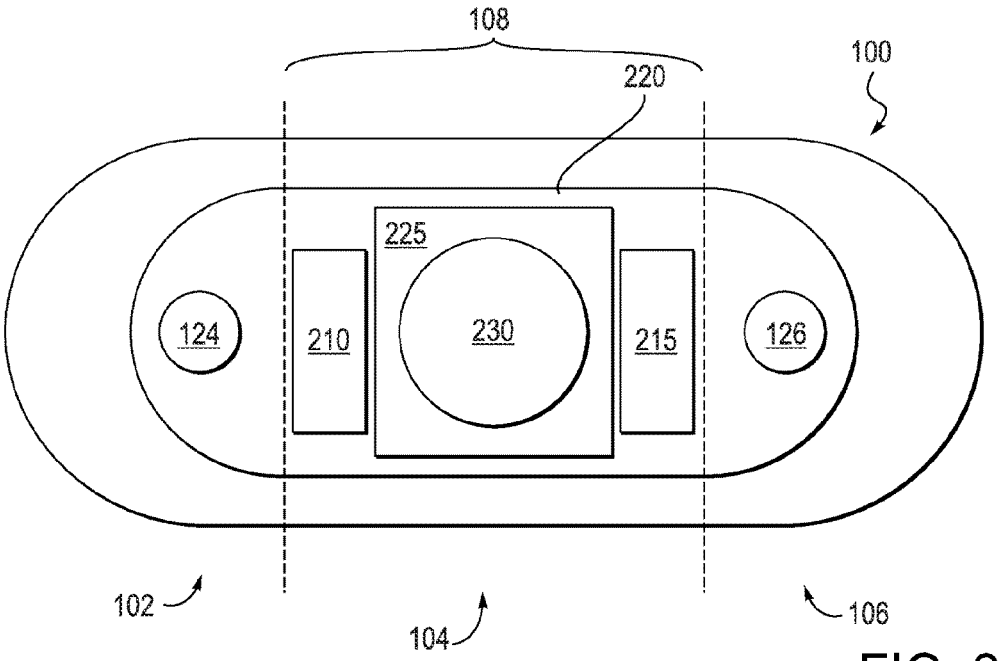


FIG. 2A

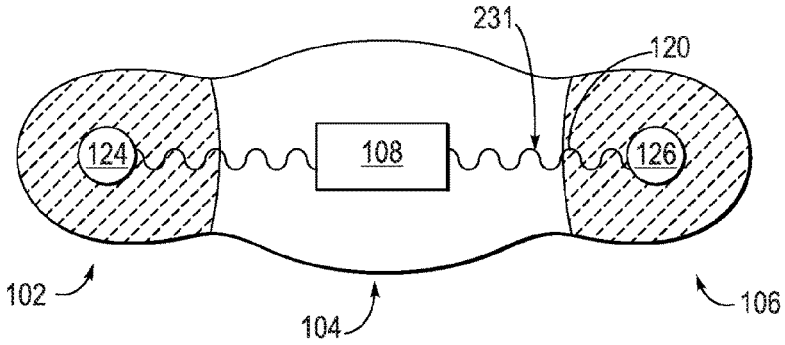


FIG. 2B

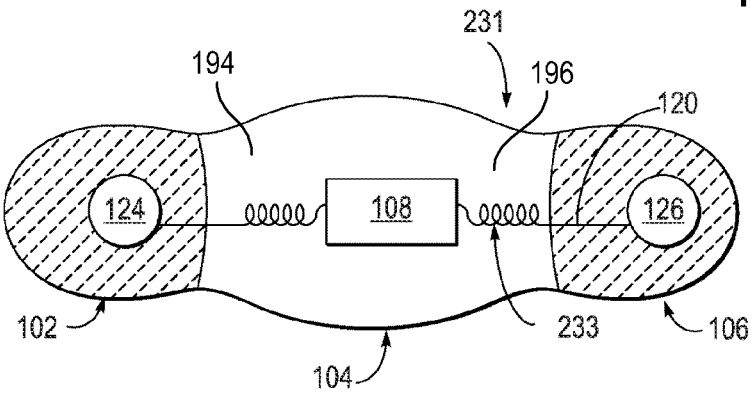


FIG. 2C

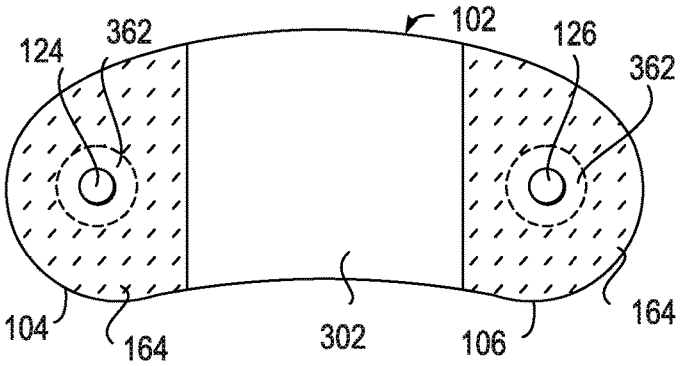


FIG. 3

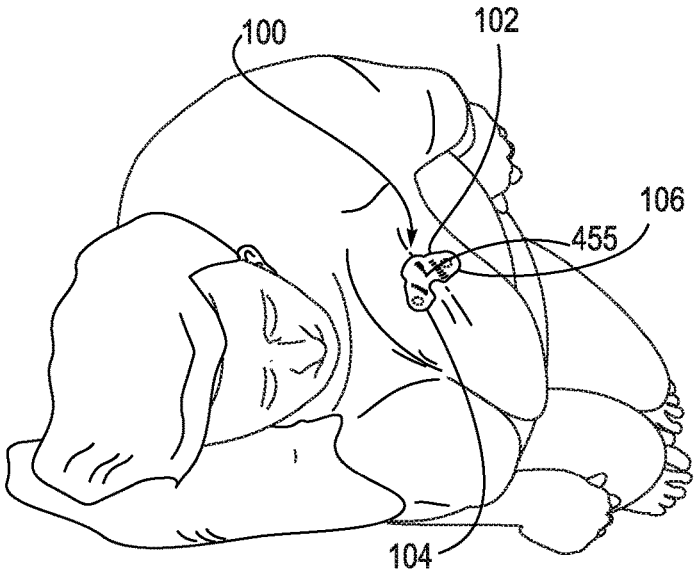


FIG. 4A

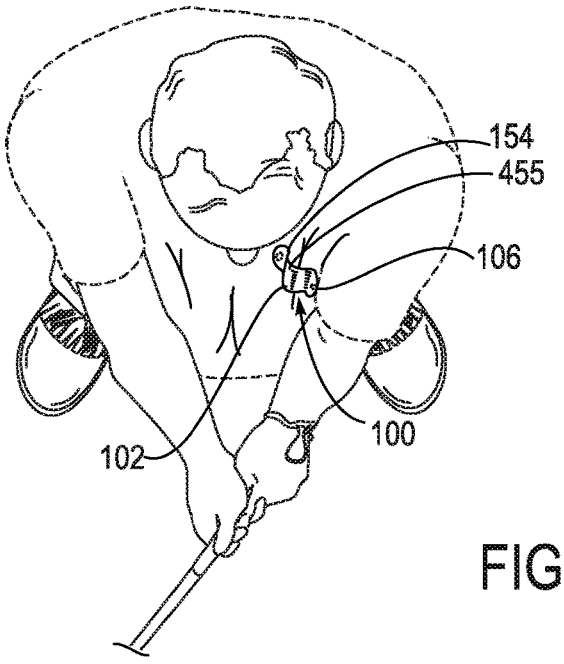


FIG. 4B

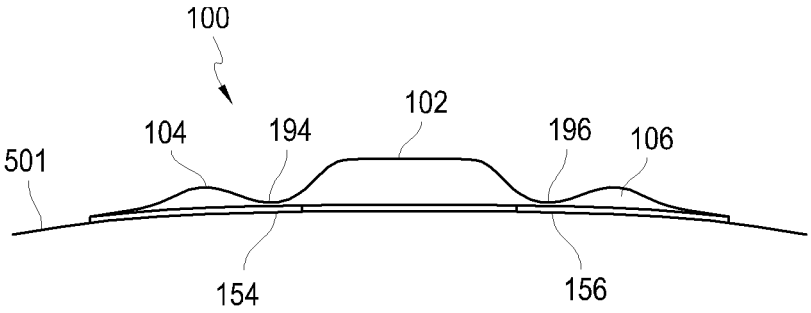
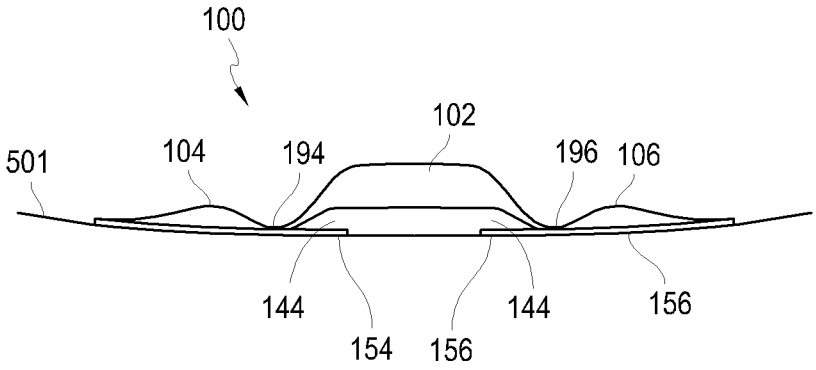


FIG. 5A



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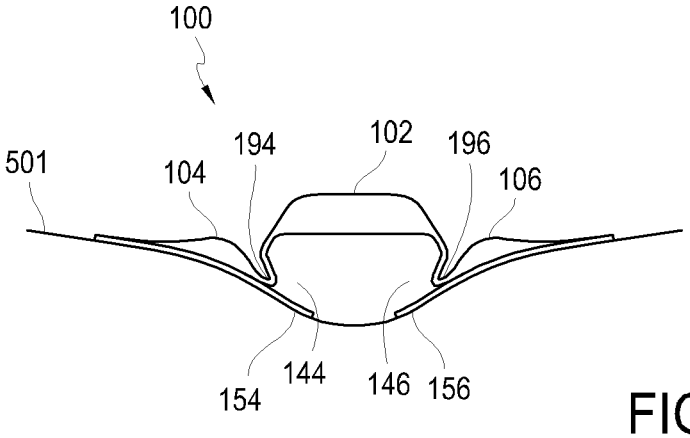


FIG. 5C

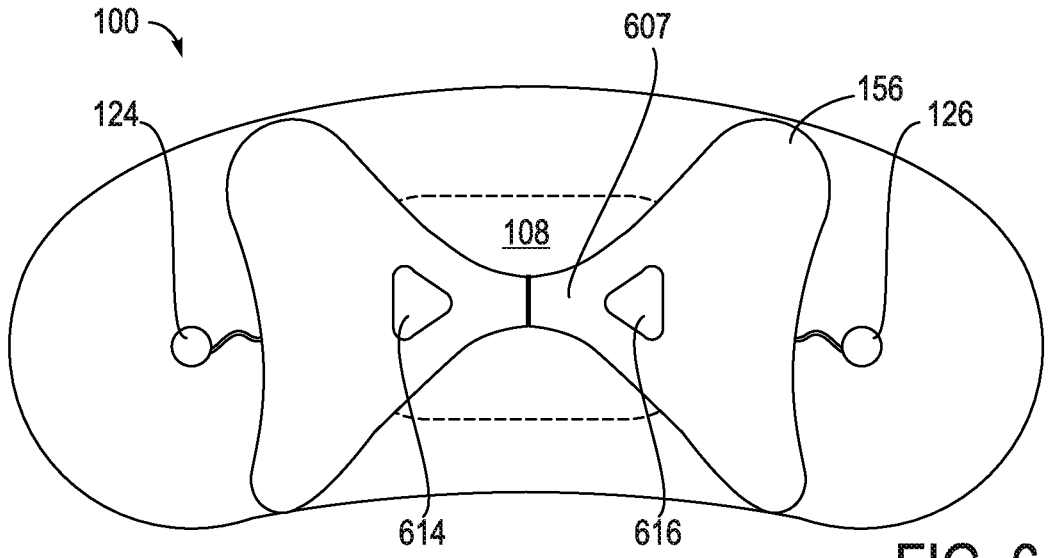
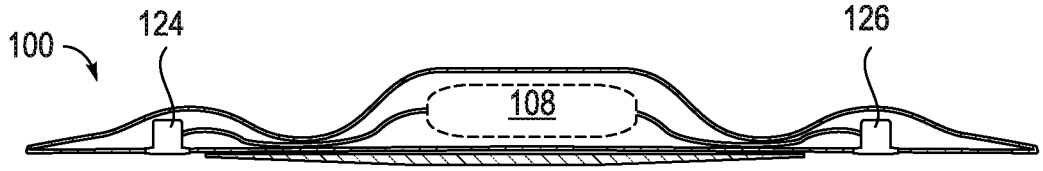


FIG. 6A



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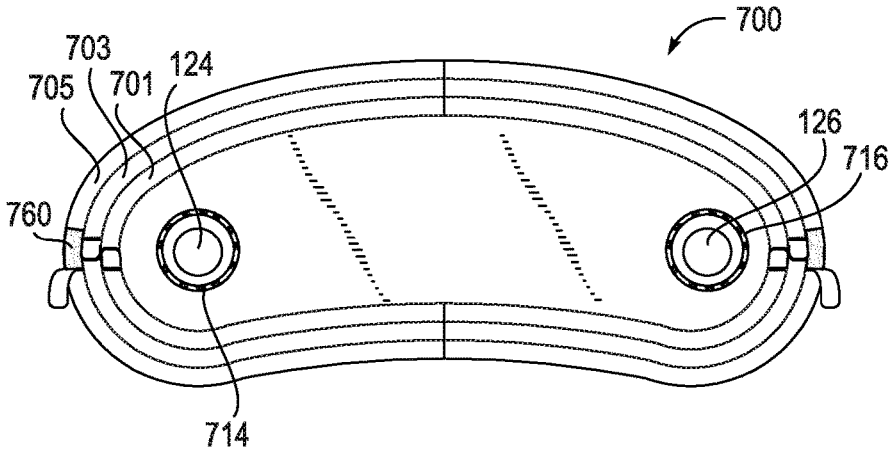


FIG. 7A

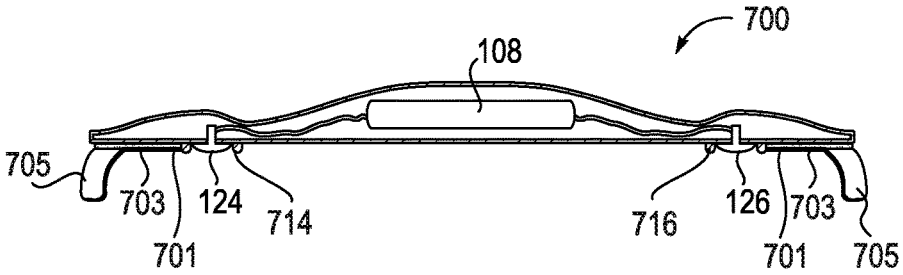


FIG. 7B

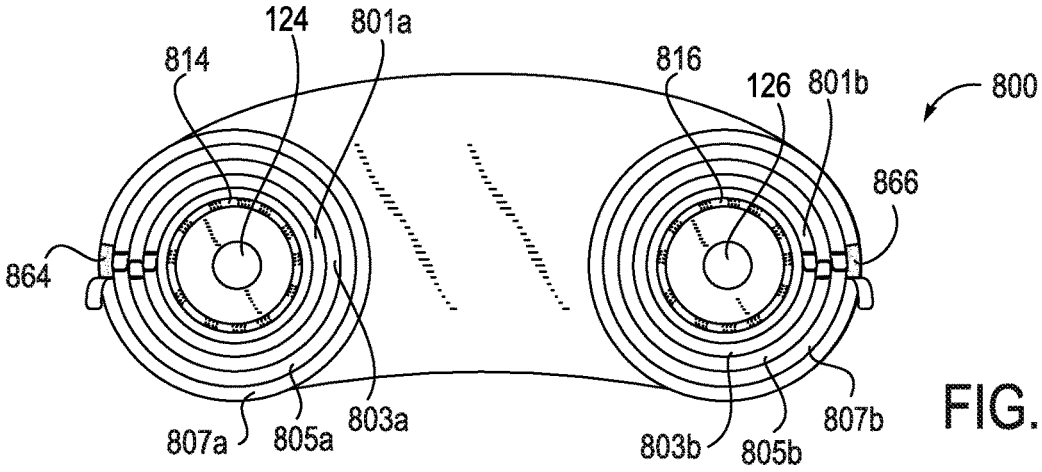


FIG. 8A

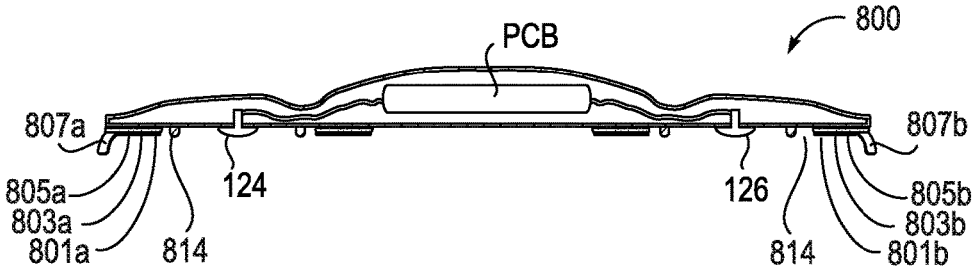


FIG. 8B

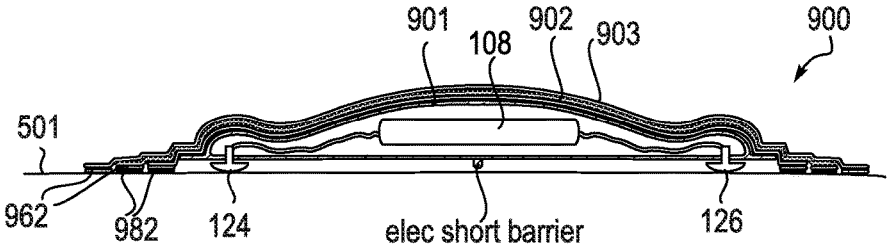


FIG. 9A

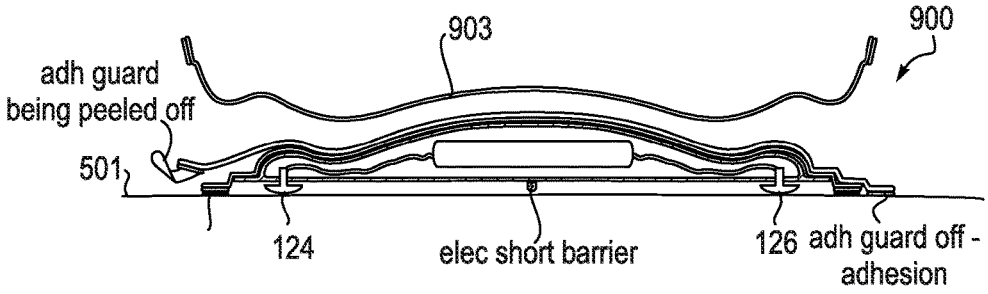
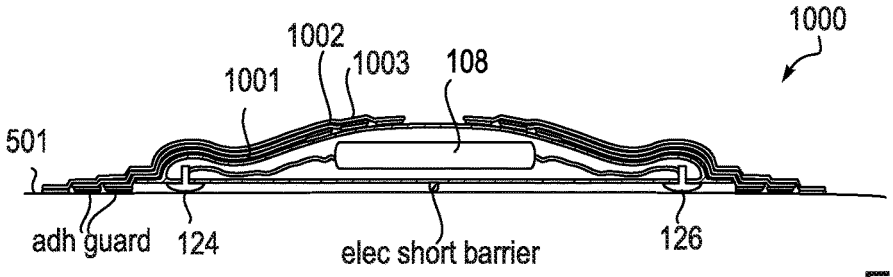


FIG. 9B



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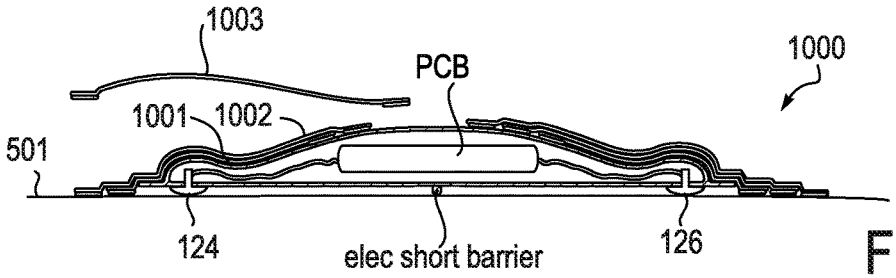

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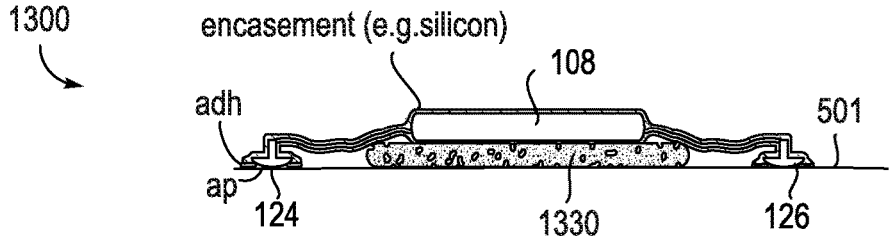

FIG. 11

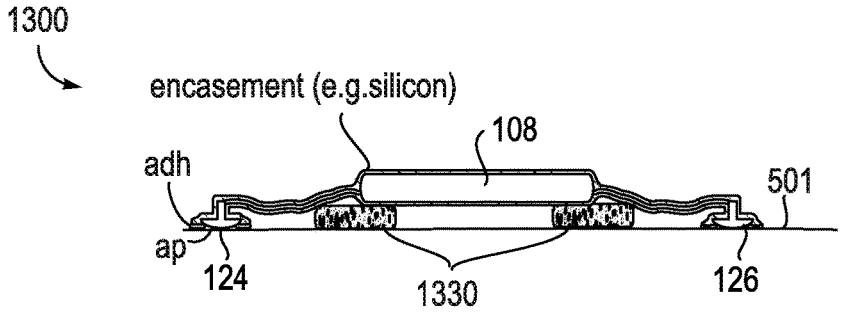

FIG. 12

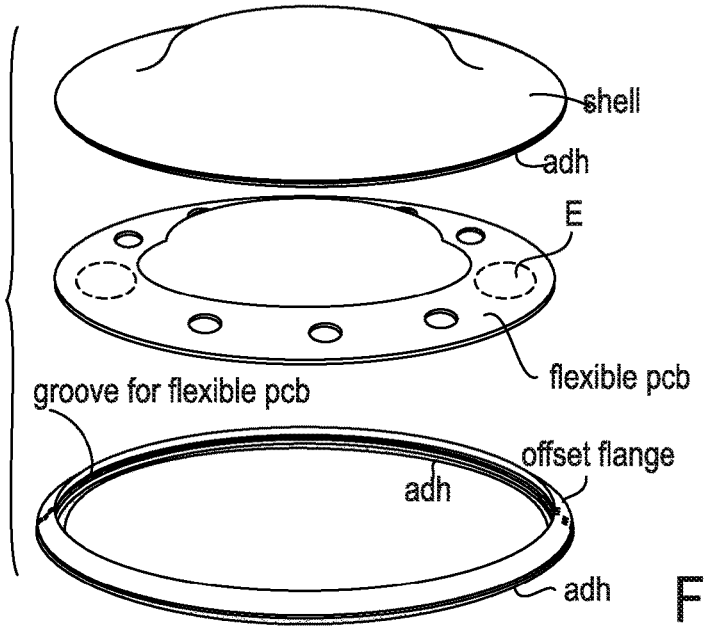

FIG. 13A

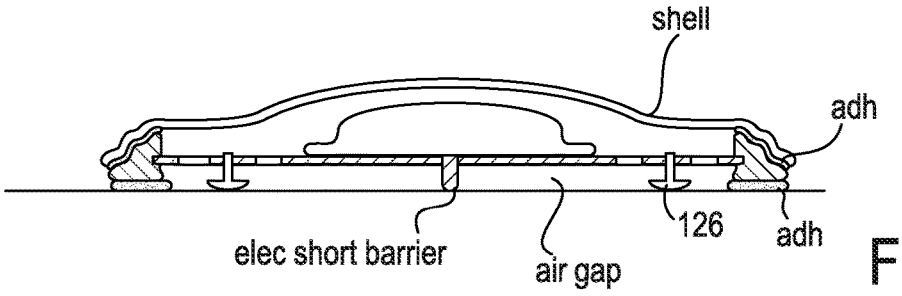

FIG. 13B

DEVICE FEATURES AND DESIGN ELEMENTS FOR LONG-TERM ADHESION

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 17/304,811, filed Jun. 25, 2021, titled "Device Features And Design Elements For Long-Term Adhesion" which claims priority to U.S. application Ser. No. 16/723,208, filed Dec. 20, 2019, titled "Device Features and Design Elements for Long-Term Adhesion" which claims priority to U.S. application Ser. No. 16/138,819, filed Sep. 21, 2018, titled "Device Features and Design Elements for Long-Term Adhesion" which claims priority to U.S. application Ser. No. 15/005,854, filed Jan. 25, 2016, titled "Device Features and Design Elements for Long-Term Adhesion" which claims priority to U.S. application Ser. No. 13/890,144, filed May 8, 2013, titled "Device Features and Design Elements for Long-Term Adhesion" which claims priority to U.S. application Ser. No. 13/563,546, filed Jul. 31, 2012, titled "Device Features and Design Elements for Long-Term Adhesion", which claims priority to U.S. patent application Ser. No. 13/106,750, filed May 12, 2011, which claims priority to U.S. Provisional Patent Application No. 61/334,081, filed May 12, 2010, entitled "Device Features and Design Elements for Long-Term Adhesion." All of the aforementioned applications are incorporated by reference as if fully set forth herein.

INCORPORATION BY REFERENCE

All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD OF THE INVENTION

This application relates to devices worn on a body for monitoring, recording, reporting and/or treating the person wearing the device. Improvements in the device design elements and functionality are disclosed for maintaining the device in contact with and operational for extended periods of time, typically longer than 24 hours.

BACKGROUND OF THE INVENTION

The ability to adhere a medical device to a human body for a long-period of time is dependent on a variety of factors. In addition to the type and nature of the adhesive chosen, another factor is the mechanical design of the device. By design, this refers to, but is not limited to, the device shape, size, weight, flexibility, and rigidity. These design elements are influenced by a number of additional factors, including, hut not limited to, where on the body the device will attach and the duration of the attachment, moisture conditions in that area, movement conditions in that area, stretching and contraction in that area, interactions with external factors in that area such as clothing, and purposeful and/or inadvertent interaction between the person wearing the device and the device.

As many are typically used on the body for less than 24 hours, devices have not been designed that can withstand longer-term adhesion. Hence, there is a need to implement device features and design elements that have the ability to enhance the likelihood of adhesion of a device to a human body for 24 hours or more, while accommodating the functionality, shape, size, weight, flexibility, and rigidity of a given device.

SUMMARY

In one aspect of the invention, there is an electronic device for long-term adhesion to a mammal. The device has a housing containing an electronic component with a first wing and a second wing integrally formed with the housing. There is an electrode positioned on a bottom surface of each of the wings with the electrodes electrically connected to the electronic component. An adhesive layer is provided tor adhesion to a surface of the mammal. The adhesive layer is coated on a portion of the bottom surface of the wings. The adhesive layer is not coated on the electrode or on a bottom surface of the housing.

The electronic component in any of the devices described herein may include a processor having a memory with computer readable instructions to record signals from the first and second electrodes while the electronic device is attached to the mammal. The processor may be configured to only convert signals from the electrodes to digital signals, filter those signals and then store the signals in memory.

In another aspect, the device includes a flap connected to each of the wings. The flaps may extend below the housing. Additionally or alternatively, the adhesive layer is coated on a bottom surface of the flaps.

In another aspect, the device includes a connector segment In one aspect, the connector segment configured to connect the flaps together. In other aspects, the connector segment is located at least partially below the housing. Still further, the connector segment is not attached to the housing.

In one alternative, the adhesive layer is coated on a bottom surface of the flap.

In still another aspect, the adhesive for adhesion to a surface of the mammal is an adhesive that can absorb fluids. In another aspect, the adhesive that can absorb fluids is a hydrocolloid adhesive. In another aspect, the adhesive for adhesion to a surface of the mammal is a pressure-sensitive adhesive. The pressure sensitive adhesive is selected from the group consisting of: a polyacrylate, a polyisobutylene, and a polysiloxane. In one alternative, the device includes a diffusion barrier between the adhesive layer and each of the wings. The device may also include an additional adhesive layer and material layer between the wing and the adhesive layer for adhesion to the mammal. The material layer is configured to prevent diffusion of adhesive components from the adhesive layer to the wing. The diffusion barrier may be made from polyester or other suitable synthetic material.

In one aspect of the device, all or substantially all of the electronic components are within the housing. In another aspect, the wing is free from electronic components. In one aspect, the wing is more flexible than the housing. In one alternative, the wings and the housing are made from the same material. In another aspect, the wings and the housing are made from different materials. In another, the wings are made from a fabric. In still another aspect, the material used to make the wings includes a synthetic fiber. In another alternative, the wing and the flap are composed of the same material.

In another alternative, the device includes a hinge portion between the housing wmg, The hinge portion is configured to allow the device to bend between the housing and the wmg. In one aspect, the hinge portion exists between a rigid

portion of the device and a flexible portion of the device. In one alternative, the rigid portion of the device corresponds to the portion of the housing including the electronics and the flexible portion of the device includes a wmg

In one aspect, the bottom surface of the wing and the bottom surface of the flap are contiguous, In another aspect, the bottom surfaces of the wings, the flap, and the connectors are contiguous. In still other aspects, the flaps and the connector are contiguous.

In another aspect, the connector has at least one hole extending it. The hole may have any of a number of shapes such as circular, oval, round, or triangular.

In one aspect, the housing is thicker at a center of the housing than at edges of the housing.

In another aspect of the device, the housing is unattached to the mammal when the electrodes are in contact with the mammal.

In another alternative aspect of a device for long-term adhesion to a mammal, the device includes a housing with a first wing extending laterally from the housing and a second wing extending laterally from the housing without overlapping the first wing, There is a first electrode positioned on a bottom surface of the first wing and a second electrode positioned on a bottom surface of the second wing. An electronic memory is positioned within the housing. The electronic memory is configured to receive and store electronic signals from the first and second electrodes while the electronic device is attached to the mammal. There is also an adhesive layer on a portion of a bottom surface of the first wing and the second wing. The adhesive is not on a bottom surface of the housing. When the device is worn on the mammal, only the adhesive layer(s) are attached to the mammal.

In one aspect, the portion of the bottom surface of the first wing and the second wing does not include the first and second electrodes, In one device aspect, the first wing, the second wing, and the housing are formed from the same material. In still another, the first wing, the second wing and the housing integrally form a monolithic structure. In other aspects, an angle formed by the first wing, the second wing, and the housing is between approximately 90° and 180°, In one variation, the angle is approximately 180°, In another variation, the angle is approximately 135°.

In still other embodiments, there is a first hinged portion between the first electrode and the processor and a second hinged portion between the second electrode and the housing.

In a further aspect, at least a portion of the body uncovered is not adhered to the mammal when signals from the electrodes are being recorded in memory.

In another aspect, the device includes a first flap connected to the first wing medial to the first electrode and a second flap connected to the second wing medial to the second electrode. Each nap may extend below the housing.

The device may also include a connector segment configured to connect the flaps together. In one aspect, the connector segment is located at least partially below the housing, but is not attached to the housing.

In another aspect, there is an electronic device that has a patch including a housing containing an electronic component. There is an electrode positioned on a bottom surface of the patch, the electrode electrically connected to the electronic component. There is a first adhesive strip extending around the perimeter of the patch and a second adhesive strip extending around the perimeter of the first adhesive strip, In one aspect, the first adhesive cover over the first adhesive strip and a second adhesive cover over the second adhesive strip, The first and second adhesive covers may be configured to be separably removed from the first and second adhesive strips, In one alternative, the first adhesive strip extends between the first and second adhesive covers. In another alternative, the adhesive in the first and the second adhesive strips is an adhesive that can absorb fluids. In still another aspect, the adhesive that can absorb fluids is a hydrocolloid adhesive. In one alternative, the adhesive in the first and the second adhesive is a pressure-sensitive adhesive. In some aspects, the pressure-sensitive adhesive is a polyacrylate, a polyisobutylene, or a polysiloxane.

In one alternative, the second adhesive strip partially overlaps the first adhesive strip. In another aspect, the second adhesive strip is attached to a shell, the shell overlapping the first adhesive strip.

In still another alternative device for long-term adhesion to a mammal, the device includes a patch having a housing with an electronic component contained therein, There is an electrode positioned on a bottom surface of the patch, The electrode electrically connected to the electronic component There is a porous foam pad configured to be positioned between the electronic component and the mammal. In one aspect, the porous foam pad comprises a biocompatible foam material. In one variation, the porous foam pad can absorb fluids. In still another aspect, the porous foam pad is attached to the housing. In another, the porous foam pad is configured to be attached to the mammal. In another request, the porous foam pad can absorb fluids.

In one aspect of a method of applying an electronic device, there is a step of removing a first adhesive cover from the first wing of the electronic device to expose an electrode and an adhesive coated on a bottom surface of a first wing, There is a step of placing the exposed electrode into contact with the mammal by adhering the adhesive coated bottom of the first wing to the mammal. There is also a step of removing a second adhesive cover from the second wing of the electronic device to expose an adhesive coated on a bottom surface of the second wing and another exposed electrode, There is also a step of placing the another exposed electrode into contact with the mammal by adhering the adhesive coated bottom of the second wing to the mammal. After performing the removing and the placing steps, the housing is unattached to the mammal, but is held in position on the mammal using the adhesive coated bottoms of the first and the second wings.

In one alternative method of attaching a device, the electronic device includes a first nap connected to the first wing and a second flap connected to the second wing. The first and second flaps each extend below the housing. The step of removing a first adhesive cover from the first wing may also include exposing an adhesive coated on a bottom surface of the first flap. The step of removing a second adhesive cover from the second wing may also include exposing an adhesive coated on a bottom surface of the second flap.

In another alternative method of attaching a device, after performing the removing and the placing steps, the housing is held in position on the mammal using only the adhesive coated bottoms of the first wing, the second wing, the first flap and the second flap.

In an alternative aspect of a method of applying an electronic device to a mammal for long-term adhesion, the method includes removing a first adhesive cover from the first wing of the electronic device to expose an electrode and an adhesive coated on a bottom surface of the first wing. There is also a step of removing a second adhesive cover from the second wing of the electronic device to expose an

adhesive coated on a bottom surface of the second wing and another exposed electrode. There is a step of placing the exposed electrodes into contact with the mammal by adhering the adhesive coated on the bottom of the first and the second wings to the mammal, After performing the removing and the placing steps, the housing is unattached to the mammal, but is held in position on the mammal using the adhesive coated bottoms of the first and the second wings.

There is also provided a method of applying an electronic device to a mammal for long-term adhesion wherein the electronic device includes a patch. The patch includes an electronic component along with an electrode positioned on a bottom surface of the patch and electrically connected to the electronic component. There is a first adhesive strip extending around the perimeter of the patch and a second adhesive extending around the perimeter of the first adhesive strip. One aspect of a method of applying the device includes a step of removing an adhesive cover from the second adhesive strip of the electronic device. There is a step of applying pressure to the second adhesive strip to adhere the second adhesive strip to the mammal such that the electrode is in contact with the mammal. Then, after a period of time, removing an adhesive cover from the first adhesive strip of the electronic device. Next, there is the step of applying pressure to the first adhesive strip to adhere the first adhesive strip to the mammal such that the electrode remains in contact with the mammal.

In another alternative method of applying an electronic device to a mammal for long-term adhesion, the electronic device includes a patch, an electronic component, and an electrode positioned on a bottom surface of the patch and electrically connected to the electronic component. There is a first adhesive strip extending around the perimeter of the patch. The method includes a step of applying pressure to a first adhesive strip to adhere the first adhesive strip to the mammal such that the electrode is in contact with the mammal. After a period of time, placing a second adhesive strip around the perimeter of the first adhesive strip. Then there is the step of applying pressure to the second adhesive strip to adhere the second adhesive strip to the mammal such that the electrode remains in contact with the mammal.

Any of the above described devices may include additional aspects. A device may also include a first wire connecting the first electrode and the processor or an electronic memory and a second wire connecting the second electrode and the processor or an electronic memory. The first and second wires extend within the body and the first and second wings. In one aspect, the first and second wires extend within and are completely encapsulated within the body and the first and second wings. In one aspect, a conduit is provided within the body and the wings and the wires pass through the conduit. In one alternative, the conduit extends from the processor or electronic memory to an electrode so that the wire is completely within the conduit. In still other aspects of the devices described above, the first and second wires connecting the electrodes to the processor or electronics each include slack between the electrode and the processor. In one aspect, the slack is located in a portion of each wing that is configured to bed or flex. In another aspect, the slack is a portion of the wire within the wing and at least partially coiled about the first or the second electrode. In still other aspects, the slack is provided by a portion of the wire formed into a coil, a wave pattern, or a sinusoidal pattern along its length the connection point on the electronics to the connection point on the electrode.

In still other alternatives, the devices described above may be applied to any of a wide variety of conventional physiological data monitoring, recording and/or transmitting devices. Any of the improved adhesion design features and aspects may also be applied to conventional devices useful in the electronically controlled and/or time released delivery of pharmacological agents or blood testing, such as glucose monitors or other blood testing devices. Additional alternatives to the devices described may include the specific components of a particular application such as electronics, antenna, power supplies or charging connections, data ports or connections for down loading or off loading information from the device, adding or offloading fluids from the device, monitoring or sensing elements such as electrodes, probes or sensors or any other component or components needed in the device specific function. In still other aspects, the electronic component in any of the above devices is an electronic system configured for performing, with the electronic signals of the mammal detected by the electrodes, one or more or any combination of or the following electronic functions: monitoring, recording, analyzing, or processing using one or more algorithms electronic signals from the mammal. Still further, any of the devices described above may include appropriate components such that the device is used to detect, record, process or transmit signals or information related to signals generated by a mammal to which the device is attached including but not limited to signals generated by one or more of EKG, EEG and/or EMG.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. **1** is a top view of a patch having two wings;

FIG. **1**A is a representative cross-section of an embodiment of the patch in FIG. **1**;

FIG. **1**B is a representative cross-section of another embodiment of the patch in FIG. **1**;

FIG. **1**C is a representative cross-section of another embodiment of the patch in FIG. **1**;

FIG. **1**D is a representative cross-section of another embodiment of the patch in FIG. **1**;

FIG. **1**E is a representative cross-section of another embodiment of the patch in FIG. **1**;

FIG. **1**F is a top view of a patch having three wings illustrating an alternative electrode-electronics-electrode orientation;

FIG. **2**A is a schematic drawing of the electronics contained within a patch;

FIG. **2**B is a schematic drawing of a patch with wiring having slack in the form of undulations between electronics and electrodes;

FIG. **2**C is a schematic drawing of a patch with wiring having slack in the form of a coil between electronics and electrodes;

FIG. **3** is the bottom view of a patch having adhesive thereon;

FIG. **4**A shows a patch as worn by a person rolled to the side;

FIG. **4**B shows a patch as worn by a person playing golf;

FIG. **5**A shows a patch in response to a concave bend of the skin;

FIGS. **5**B and **5**C show a patch in response to a convex bend of the skin;

FIG. **6**A is a bottom view of a patch having a connector between two flaps;

FIG. **6**B is a cross-section of the patch of FIG. **6**A;

FIG. **7**A is a bottom view of a patch having multiple covers forming strips of adhesive;

FIG. **7**B is a cross-section of the patch of FIG. **7**A;

FIG. **8**A is a bottom view of a patching having multiple covers forming strip of adhesive around each electrode;

FIG. **8**B is a cross-section of the patch of FIG. **8**A;

FIGS. **9**A and **9**B show a patch having multiple layers formed thereon;

FIGS. **10**A and **10**B show a patching having multiple layers formed thereon, each layer having multiple patches of adhesive;

FIG. **11** shows a patch having an open cell support;

FIG. **12** shows a patch having an annular open cell support;

FIG. **13**A shows a patch having a protective shell thereon; and

FIG. **13**B shows a cross-section of the patch of FIG. **13**A.

DETAILED DESCRIPTION

The following device features and design elements can be implemented into any device being adhered to the human body for a long-period of time, typically greater than 24 hours. As an example, the following device features and design elements can be used for long-term adhesion of a cardiac rhythm monitoring patch ("patch") to the chest of a person.

Referring to FIGS. **1** and **1**A, a patch **100** for long term adhesion includes a housing **102**. The housing **102** can be formed from any flexible, durable material, such as a biocompatible polymer, for example silicone. The housing **102** can include electronic components **108** therein. As shown in FIG. **2**, the electronics **108** can include a printed circuit board **220**, a battery **225**, and a communications port mounted on the printed circuit board **220**. The printed circuit board **220** can include analog circuits **210**, digital circuits **215**, and an activation or event notation button or switch **130**. The electronics **108** can be used, for example, to record continuous physiological signals from a mammal wearing the patch **100**. A system for continuously recording data is described further in co-owned U.S. application Ser. No. 11/703,428, filed Feb. 6, 2007, the entire contents of which are incorporated by reference herein.

As shown in FIGS. **1** and **1**A, wings **104**, **106** can be connected to the housing **102**. The wings **104**, **106** can be integral with the housing **102** and, in some embodiments, can be formed of the same material as the housing **102**. The wings **104**, **106** can be more flexible than the electronic components **108**, which can be substantially rigid. An electrode **124**, **126** can extend through a bottom surface of each wing **104**, **106**. The electrodes can be positioned to detect an ECG of a mammal wearing the patch **100** for processing by the electronics **108**. For example, the electrodes can be more than 2 cm apart, such as more than 3 cm apart, for example at least 6 cm apart. The electrodes **124**, **126** can be integral with the wings **104**, **106** so as to be inseparable from the wings **104**, **106** when the patch is in use.

For a patch **100** that is entirely flexible and can conform, stretch, and adapt to the movement and conditions of the chest underneath the device, adhesive can be placed over the entire surface of the device that is in contact with the body, except for areas where sensors, electronics, or others elements such as electrodes are interacting with the body related to the functioning of the device may be incorporated. Thus, as shown in FIG. **3**, an adhesive layer **166** can coat the bottom of the patch **100** for attachment to the skin, For a patch **100** in which there may be some areas that are not completely flexible and may not be able to stretch or contract (e.g., the electronics **1**(**8**), adhesive may be excluded from the portion of the patch **100** underneath these areas. Thus, for example, the bottom surface **302** of the housing **102**, which contains the electronics, can remain free from adhesive. As shown in FIG. **1** A, by not coating adhesive on a bottom surface of the housing **102**, the housing **102** can float above the adhered portions, allowing for increased flexibility of the patch, as will be discussed further below. Further, as shown in FIG. **3** the bottom surface of the electrodes **124**, **126** can remain free of adhesive. For example, a ring **362** without adhesive can be formed around each electrode **124**, **126** to separate the electrodes from the adhesive **164**, The adhesive can be, for example, a pressure-sensitive adhesive, such as polyacrylate, polyisobutlene, or a polysiloxane. Alternatively, the adhesive can be a hydrocolloid which advantageously absorbs water.

The wings **104**, **106** and the housing **102** can form a smooth, contiguous outer surface to the patch **100**, As shown in FIG. **1** A, when viewed from the top, the housing **102** and wings **104**, **106** can together form an oblong substantially oval shape, Further, the housing **102** can have a thickness that is greater than the thickness of the wings **104**, **106**. The housing **102** and each of the wings **104**, **106** when viewed in profile, can each form a dome with a height that is greater at the center than at the ends of the respective component, i.e. some or all of the components can be tapered at the ends and/or sides.

The electronics **108** can extend along only a portion of the distance between the electrodes **104**, **106**. For example, the electronics can occupy less than 90% of the distance between the electrodes, for example less than 80%. By having the electronics **108** in a relatively limited space between the electrodes **124**, **126**, the flexibility of the patch **100** can be increased

The housing **102** can provide a watertight enclosure **110** for electronic components **108** of the patch **100**, The electronics **108** can be unattached to the housing **102** such that the electronics **108** are free to move within the watertight enclosure **110**. Allowing the relatively rigid electronics **108** to move freely within the flexible housing **102** advantageously enhances the overall flexibility of the patch **100**, The wings **104**, **106** can each have a watertight enclosure **114**, **116** formed therein, which can be contiguous with the watertight enclosure **110** of the housing **102**.

Wiring **120** or other suitable electrical connections can connect the electrodes **124**, **126** with the electrical components **108** of the housing. In some embodiments, as shown in FIGS. **1**B-IE, the contiguous nature of the enclosure **110** and the enclosures **114**, **116** allows the wiring **120** to extend within the patch **100** from the electrodes **124**, **126** to the electronic components **108**. In other embodiments, one or more channels, tubes, or conduits are provided between the housing **102** and the wings **104**, **106**, to provide space for the wiring **120**. The tube or channel may be straight or curved. In use, the wire **120** positioned in the enclosures **110**, **114**, **116** or in the tube or channel may move relative thereto in order to remain flexible within the housing. In one aspect, the flexible channels or tubes are formed within the device housing so that the housing, as it is being stretched, does not affect the ability of the components, such as wires, that may connect more rigid structures, to move or elongate.

As shown in FIG. **1**, the wire **120** is straight with a direct line of connection between the electrodes **124**, **126** and the

electronics **108**. FIG. **1** illustrates an embodiment where the length of the wires **120** connecting the electrodes **124**, **126** to electronics **108** are about the same distance as the spacing between the electrode connection point on electronics **108** and the electrodes **124**, **126**. FIG. **1**F also illustrates a straight line type connection where wire **120** length is nearly the same as the spacing between the electronics **108** and the electrodes **124**, **126**. However, as a patient moves, the patch **100** flexes along with patient movement. As shown in FIGS. **4**B and **5**C, patch flexion may be severe and is likely to occur during long term monitoring. In order to address the possible dislocation or breakage of the wire **120**, the length or shape of the wire **120** may be selected to permit patch flexion to occur with little risk of wire **120** pulling from the electrode or electronics. Numerous alternatives are possible to compensate for patch flexion. Exemplary confirmations include undulations or zig-zags **231** as shown in FIG. **2**B, coils **233** as shown in FIG. **2***e*, or a configuration that partially or fully wraps around an electrode. In some embodiments, other components, such as the circuit hoard or electrodes, can alternatively or additionally contain additional length to help accommodate stretch or displacement. When the patch **100** is attached to a mammal, the slack in the wiring **120** allows the patch **100** to flex while not placing stress on the wiring **120**.

While the illustrated embodiments of FIGS. **1**A-**1**D show only two wings and show the electrodes and electronics in a direct line in a approximate 180 degree alignment of electrode **124** to electronics **108** to electrode **126**), other configurations are possible. For example, as shown in FIG. **1**F, the wings **104**, **106** are arranged in an orientation less than 180 degrees. In the illustrated embodiment, the angle formed by the electrodes and the electronics is about 135 degrees. Other ranges are possible so long as electrode spacing is provided to permit ECG monitoring. The orientation of the wings **104**, **106** to the housing **102** also illustrates the use of an additional adhesive tab **105**. Tab **105** is shown as a semicircular extension of the body **102**. The bottom of tab **105** can include adhesives as described herein and is used to provide additional anchoring of the patch to the patient. The tab **105** may be formed in any of a number of different shapes such as rectangles, ovals, loops or strips. Further, in some embodiments, the tab **105** can function similar to a wing, e.g., include an electrode therethrough that connects to the electronics **108**.

Referring to FIGS. **1**A-**1**D and **2**B-**2**C, a hinge portion **194**,**196** in the patch **100** can extend between each electrode **124**, **126** and the electronics **108**. The hinge portions **194**, **196** can have a thickness less than the thickness of surrounding portions of the patch **100**, For example, if the hinge portions **194**, **196** are in the wings **104**, **106**, then the thickness can be less than adjacent portions of the wings. Likewise, the hinge portions **194**, **196** can have a width less than adjacent portions of the patch **100**, e.g., less than adjacent portions of the wings **104**, **106**. Alternatively, the hinged portion can be formed by the adjunct between a rigid portion, i.e. the electronics **108**, and a more flexible portion, The hinged portion allows the patch **100** to bend between the housing **102** and wings **104**, **106** to compensate for any movement caused by the patient. As shown in FIGS. **2**B and **2**C, the slack in the wiring **120** can be placed at or proximal to the hinge portions **194**, **196** to allow for bending at the hinge portions **194**, **196** without pulling or breaking the wiring **120**.

Referring to FIGS. **4**A and **4**B, having adhesive on the bottom of the patch **100** except in the areas substantially around the electrodes and directly underneath the housing **102** can create a floating section **455** over the skin of the mammal to which the patch **100** is attached. The floating section **455** can house the more rigid or less flexible electronic components while the flexible wings **104**, **106** can be adhered to the skin and provide the flexibility necessary to hold the patch **100** in place. As a result of this selective use of adhesive areas and non-adhesive areas, the limitation on device flexibility imposed by the less flexible floating section can be mitigated or reduced by hounding the floating section with one or more adhered flexible areas. The flexible sections can thus adhere to the body if the underlying portion of the body is stretched and/or contracted while the floating section is free to move above the skin, for example if the person wearing the device rolls over (as shown in FIG. **4**A) or is involved in activities that can otherwise cause movement of the skin (as shown in FIG. **4**B).

Referring back to FIGS. **1**B-**1**E, each wing **104**, **106** can include a material layer **214**,**216** between the adhesive **164**, **166** and the wings **104**, **106**, The material layer **214**,**216** can be, for example, a polyester layer. The material layer **214**, **216** can be attached to the patch **100** with a layer of adhesive **204**,**206**, The adhesive **204**, **206** can be the same as the adhesive **164**, **166** or different. For example, the adhesive **204**, **206** could be a silicone adhesive. The material layer **214** can serve as a barrier to prevent diffusion or migration of adhesive components, such as a tackifier, from the adhesive **164**, **166** into the wings **104**, **106** or housing **102**. The material layer **214** can thus advantageously serve to maintain the strength of the adhesive **104**, **106** over time.

Referring still to FIGS. **1**B-IE, the patch **100** can further include a first flap **154** connected to the first wing **104** and a second flap **156** connected to the second wing **106**. The flaps **154**, **156** can both extend from a position on the wings **104**, **106** medial to the electrodes to a position below the housing **102**, such as below the electronics **108**. The flaps **154**, **156** can remain unattached to the housing **102**. As a result, gaps **144**, **146** can be formed between the flaps **154**, **156** and the housing **102**. The gaps can provide additional "floating" for the housing **102** and the relatively rigid components **108** contained therein.

In some embodiments, shown in FIG. **1**B, the flaps **154**, **156** can be attached to the wings **104**, **106** with adhesive **134**, **136**. The adhesive **134**, **136** can be the same as the adhesive **164**, **166** or different. For example, the adhesive **134**, **136** could be a silicone adhesive. In other embodiments, shown in FIGS. **1**C-IE, the flaps **154**, **156** can be integral with the wings **104**, **106**. For example, the flaps **154**, **156** can be solvent welded to and/or formed during the molding process of the wings **104**, **105** such that hinges **194**, **196** form below the wings **104**, **106**. Additionally or alternatively, one or more of the flaps **154**, **156** may be separably attached to the wings **104**, **106**. In some embodiments, shown in FIGS. **1**B and **1**C, the materials making up the flaps **154**, **156** can extend all the way to the lateral edge of the patch **100**. In other embodiments, shown in FIG. **1**D, a flap can extend on each side of the electrodes, i.e. one flap can extend medially and the other laterally. In some embodiments, the lateral and medial-extending flaps are part of the same annular flap. In other embodiments, shown in FIG. **1**E, the flaps and materials making up the flaps extend only from a position medial to the electrodes underneath the housing.

The Flaps **154**, **156** may be positioned in virtually any relationship to the adhered flexible area such that, when attached in use, the attachment of the flap or flaps effectively counteracts the expected external forces acting on the device, specifically those forces that may dislodge the adhered flexible areas. Further, in embodiments such as that

shown in FIG. **1**F where there are more than two wings, there can be a flap corresponding to each additional wing.

The adhesive layers **164**, **166** can coat all or a portion of the bottom of each of the flaps **154**, **156**. In some embodiments, the adhesive **164**, **166** extends continuously from the bottom surface of the wings **104**, **106** to the bottom surface of the flaps **154**, **156**, except for areas proximate to the electrodes **124**, **126**. Further, the top surface of the flaps **154**, **156**, i.e. the surface closest to the housing **102**, can remain free of adhesive to ensure that the housing **102** remains floating. In some embodiments, the only portion of the patch **100** including adhesive for adhesion to the skin can be the flaps **154**, **156**.

Referring to FIGS. **5**A-**5**C, the naps **154**, **156**, can provide hinge-like behavior for the patch **100**, Thus, as shown in FIG. **5**A, if the skin **501** is stretched or bent in a concave manner, the gaps **144**, **146** between the flaps **154**, **156** and the housing **102** can approach zero such that the patch **100** can sit substantially flat on the skin **501**. As shown, the hinge portions **194**, **196** between the housing **102** and wings **104**, **106** can provide additional flexibility for concave bends by flattening as the patch **100** is stretched. In contrast, as shown in FIGS. **5**B and **5**C, as the skin **501** is bent in an increasingly convex manner, the gaps **144**, **146** between the flaps **154**, **156** and the housing **102** can increase, thereby allowing the flexible wings **104**, **106** to remain adhered to the skin and the rigid housing **102** to float above skin. As shown, the hinge portions **194**, **196** between the housing and the wings **104**, **106** can provide additional flexibility for convex bends by folding inward as the patch **100** is bent.

When placed substantially flat on the skin **501**, the patch **100** can have a height that extends no more than 2 cm off of the skin, such as no more than 1.5 cm off of the skin, when lying flat on the patient and no more than 4 cm, such as no more than cm off of the skin when floating above the skin. The relatively low height of the patch **100** can enhance long-term adhesion by reducing the potential for the patch] **00** to snag or rip off of the skin.

Advantageously, the flaps **154**, **156** can function as anchors for adhesion that mitigates shear force. The flaps **154**, **156** can provide a different direction for the acute and chronic forces being experienced by the device due to stretching, contraction, or torsion to be spread out over both the flap as well as the flexible adhesive areas. Further, by pre-aligning the orientation of the floating section, adhered flexible area and the flaps, the device may be better able to tolerate (i.e., remain attached to the body and in use) and/or tailor the interaction with the forces acting on the device in order to better withstand the acute or chronic forces being experienced by the device. Tailoring the response of the device to the expected forces is one

Because the flaps can be used to counteract forces acting on a particular device, it is to be appreciated that the dimensions, flexibility, attachment technique, and/or orientation between a flap and another component may vary depending upon the purpose of a particular flap. Accordingly, a flap may have the same or different characteristics from another flap or component of the device. In one aspect, at least one flap is more flexible that the other flaps in a particular device. In another aspect, each of the flaps has similar flexibility. In still another aspect, at least one flap is more flexible than the device component to which it is attached or from which it originates. In still another aspect, at least one flap is less flexible than the device component to which it is attached or from which it originates.

Referring to FIGS. **6**A and **6**B, in one embodiment, the flaps **154**, **156** may be augmented by a connector segment **607** used to join the flaps together. The connector segment **607** can extend below the housing **102**, but remain unattached to the housing **102**. As shown in FIG. **6**A, the flaps **154**, **156** and the connector **607** can together form a butterfly shape. In one embodiment, the connector segment **607** and the flaps **154**, **156** are formed from a single piece of material. The connector segment **607** can be made of the same material as the flaps **154**, **156** or of different material. In one embodiment, the bottom surface of the connector is covered with adhesive. In another embodiment, the bottom surface of the connector does not include any adhesive. Further, as shown in FIG. **6**B, the connector segment **607** can be thicker in the middle, under the housing **102**, than near the edges, i.e., closer to the electrodes. The variable thickness can help prevent the connector segment **607** from capturing moisture thereunder. The connector segment **607** can advantageously prevent the device from flipping when attached to the patient

The connector segment **607** can include one or more holes **614**, **616**. In some configurations, the connector segment may trap moisture and/or inadvertently stick to the body. The holes **614**, **616** can advantageously minimize the potential for undesired sticking or moisture collection. The size, shape and placement of the holes mitigate or reduce the collection of moisture and/or undesired adhesive still providing a connector with sufficient structural integrity (i.e. the connector allows the flaps to be connected to one another in order to prevent them from folding). Additionally or alternatively, the connector holes could also be made to preferentially allow forces to be distributed along certain axes of the connector in order to further maximize the ability of the device to adhere tong-term in the face of significant acute and chronic forces due to stretching, contraction, and torsion.

Adhesive can be selectively applied to the connector and/or naps to provide the desired body attachment locations depending upon the specific use of the device. For example, one piece of material including flaps and the connector can be adhered along two or more edges and/or with adhesive only covering certain areas, In another aspect, at least a portion of the skin-contacting surface of the unitary nap connector structure does not include any adhesive. Additionally or alternatively, the connector segment incorporating the flaps may be integral parts of the larger device housing (e.g. could be molded as part of the device housing or enclosure).

In some embodiments, the patch **100** can include one or more release liners to cover parts of the adhesive prior to adhesion. As is particular to devices having multiple adhesive areas and/or multiple adhesive components (i.e., flaps and flexible sections), the manner of applying the device may be specifically detailed in order to ensure that the device and the adhesive portions are properly engaged. In one particular aspect, the release liners are removed in a particular order to minimize the likelihood that the device adhesive is misapplied. For example, a portion of the adhesive may be exposed first and used to affix the device to the body, Thereafter, a second set of adhesive liners may be removed to expose and affix one or more flaps to the body, A stepwise adhesive exposure method may be implemented during device application such that elements, such as the one or more flaps do not fold on themselves, for example.

Breaking up the areas in which the adhesive is used to adhere the device, whether it be splitting it up to rigid areas, to create flaps, to create connector segments with holes, of any of the other techniques described above may also have benefits in terms of preventing moisture bridges that could act as conducting pathways between electrical sensing ele-

ments, such as electrodes. Bridges of moisture could short-circuit electrical connections and/or prevent the proper functioning of the device, particularly if the device has an electrical function, such as sensing via electrodes.

In some applications, a long-duration patch may experience excessive forces due to acute (quick and/or rapid) or chronic (slow and/or prolonged) contraction, stretching, or torsion. In such applications, the hinge points between a floating rigid section and flexible adhered sections may be modified in order to align with and counteract or mitigate the predominant direction of the force acting on the patch. In some device situations or configurations, the strength and direction of the acute or chronic force may be so strong that the forces imparted on the device adhesive surfaces or components may be distributed differently in addition to or as an alternative to the hinge described above.

Further, the device construction can be made in such a way that the housing is fashioned so that the axes of the housing are structured and placed along or against the direction of various forces, possibly during certain states, such as sleeping, so that the device itself can help counteract these forces and improve long-term adhesion.

Advantageously, the patch described herein can provide long-term adhesion to the skin. Having the various flexible portions and/or hinged portions can compensate for stressed caused as the skin stretches or bends, while allowing the rigid portion to float about the skin. As a result, the devices described herein can adhere to the skin substantially continuously tor more than 24 hours, such as greater than 3 days, for example, greater than 7 days, greater than 14 days, or greater than 21 days.

Another mechanism for adhering a patch to the skin long-term is described with respect to FIGS. **7-10**. As shown in the embodiments of FIGS. **7-10**, one or more parts of the patch are used in a temporary fashion in order to improve adhesion. The adhesive used in the embodiments described below can include a hydrocolloid or a pressure-sensitive adhesive, such as polyacrylate, polyisobutylenes, or polysiloxane.

In one embodiment, shown in FIGS. **7**A and **7**B, the patch **700** can be surrounded with an adhesive **760** having multiple covers **701**, **703**, **705** thereon that can be peeled away in a sequence to expose strips of adhesive **760** underneath. The covers **701**,**703**,**705** can be concentric with one another and be configured to be pulled off separately and sequentially starting from the inside of the patch **700**. Each additional exposed area of adhesive **760** can increase the adhesion life of the patch **700**. Although only three covers are shown in FIG. **7** A, other numbers, such as 2, 4, 5, or more are possible. Further, each electrode **124**, **126** of the patch **700** can include a barrier **714**,**716** to protect the electrodes **124**, **126** from shortage.

In another embodiment, shown in FIGS. **8**A and **8**B, each electrode **124**, **126** can be surrounded by a patch of adhesive **864**, **866**. Accordingly, a set of covers **801**, **803**, **805**, **807** can be positioned sequentially around each of the electrodes **124**, **126** over the adhesive **864**, **866**. The covers **801**, **803**, **805**, **807** can be concentric with one another and be configured to be pulled off sequentially starting from the inside. Each additional exposed strip of adhesive **864**, **866** can increase the adhesion life of the patch **100**. Although only four covers are shown in FIG. **8**A, other numbers, such as 2, 3, 5, or more are possible. Further, each electrode **124**, **126** of the patch **800** can include a barrier **814**, **816** to protect from shortage.

Referring to FIGS. **9**A-**9**B, in other embodiments, shells or layers **901**,**902**,**903** can extend over all or a portion of the patch **900**. Each layer **901**,**902**,**903** can include a strip of adhesive **962** on the bottom surface and an adhesion guard **982** protecting the adhesive. As shown in FIG. **913**, as the patch **900** is worn over a period of time, the layers **901**, **902**, **903** can be sequentially removed. As a new layer is exposed, the adhesive guard **982** of that layer can be peeled away such that the adhesive **962** of the new layer can be used to adhere the patch **900** to the skin, In a similar embodiment, referring to FIGS. **10**A-**10**B, each of the layers **1001**, **1002**, **1003** can include multiple portions of adhesive to help adhere the layer to both the skin and the patch itself. As with the embodiments of FIGS. **7-8**, the number of layers in the embodiments of FIGS. **9** and **10** can vary. For example, there can be 2, 3, 4, or 5 or more layers.

In some embodiments, the layers or covers of the embodiments described herein can be added to the device over time to improve adhesion. Further, the multiple layers or covers of the embodiments described herein can be partially overlapped. Further, in some embodiments, the strips of adhesive can be overlapped.

Advantageously, the use of multiple covers or layers can assist in the adhesive performance of a base or core device because the added surface area or adhesive force of the combined outer layer aids in preventing layer pull away and/or may act to spread forces being experienced away from the core device by spreading those forces over a larger area.

Referring to FIGS. **11** and **12**, an open cell structured support **1330** or porous foam can be used to support a more rigid or less flexible portion **1302** of the patch **1300**, As shown in FIG. **11**, the open cell structured support **1330** can fully fill an area below the rigid portion **1302**. Alternatively, as shown in FIG. **12**, the open cell structured support **1330** can be an annular shape or have some other configuration that includes spaces between adjacent portions of the support. The open cell structured support **1302** may be attached to both the skin and to the rigid portion, to only the rigid portion, or to only the skin. Because of the open cell structure of the support, the flexible movement of the skin can be absorbed by the structure entirely or partially such that the rigid portion does not impact or has a reduced impact on the ability of the device to accommodate movement and remain affixed. In addition, the open cell support may have a thickness selected to enhance patient comfort so that the more rigid portion of a device does not push against the skin. In one aspect, the open cell structure is a biocompatible foam material. In another aspect, the open cell material is positioned between an electronics module on the device and the skin when worn by a patient. The open cell support can advantageously absorb fluids to keep the electrodes from shorting.

Referring to FIG. **13**, the patch can have a shell design. Adhesive can be placed on the perimeter edge of the bottom ring. The circuit board and electrode unit can be dropped into the bottom ring, and a shell can be dropped on top of the circuit board and electrode. The perimeter adhesive can create a watertight chamber therein.

The shape of a particular electronic device embodiment may vary. The shape, footprint, perimeter or boundary of the device may be a circle or circular (see FIG. **13**A), an oval (see FIG. **1**A, **2**A), a triangle or generally triangular (see FIG. **1**F) or a compound curve. Examples of a device embodiments having a compound curve shape are shown in FIGS. **2**B, **2**B, **3**, **6**A, **7**A, and **8**A. In some embodiments, the compound curve includes one or more concave curves and one or more convex curves. FIG. **3** illustrates a device having a convex surface along the top (where reference **102**

indicates), a concave surface along the bottom and convex shaped edges around the electrodes **124**, **126**. FIGS. **2**B and **2**C illustrate a device embodiment having a convex shape on either side of the electronics **108** and around the electrodes **124**, **126**. The convex shapes are separated by a concave portion. The concave portion is between the convex portion on the electronics and the convex portion on the electrodes, In some embodiments, the concave portion corresponds at least partially with a hinge, hinge region or area of reduced.

While described in the context of a heart monitor, the device adhesion improvements described herein are not so limited. The improvement described in this application may be applied to any of a wide variety of conventional physiological data monitoring, recording and/or transmitting devices. The improved adhesion design features may also be applied to conventional devices useful in the electronically controlled and/or time released delivery of pharmacological agents or blood testing, such as glucose monitors or other blood testing devices. As such, the description, characteristics and functionality of the components described herein may be modified as needed to include the specific components of a particular application such as electronics, antenna, power supplies or charging connections, data ports or connections for down loading or off loading information from the device, adding or offloading fluids from the device, monitoring or sensing elements such as electrodes, probes or sensors or any other component or components needed in the device specific function. In addition or alternatively, devices described herein may be used to detect, record, or transmit signals or information related to signals generated by a body including but not limited to one or more of EKG, EEG, and/or EMG.

What is claimed is:

1. An electronic device for long-term adhesion to a user, the device comprising:

a housing comprising a physiologic data collection circuit, the housing positioned over a flexible layer extending from beneath the housing, the flexible layer comprising an electrode positioned on the bottom of the flexible layer at a position distal from the housing, wherein the flexible layer comprises a polymer upper layer overlying an electrical connection, the electrical connection extending linearly from the physiologic data collection circuit to the electrode when viewed from above the electronic device, the polymer upper layer adhered to a polymer lower layer underlying the electrical connection;

a connecting adhesive layer positioned under the polymer upper layer, the connecting adhesive layer adhering the polymer upper layer to the polymer lower layer; and

a lower adhesive layer positioned on the flexible layer and configured to adhere the electronic device to a user.

2. The electronic device of claim **1**, further comprising a flap extending beneath the housing.

3. The electronic device of claim **1**, wherein the housing is rigid.

4. The electronic device of claim **1**, wherein the housing is configured to remain connected to the flexible layer when the housing is tilted at an angle relative the lower adhesive layer in response to movement of the user.

5. The electronic device of claim **1**, further comprising a hinge portion adjacent the housing.

6. The electronic device of claim **1**, wherein the lower adhesive layer comprises a hydrocolloid adhesive.

7. The electronic device of claim **1**, wherein the physiologic data collection circuit is configured to collect cardiac rhythm data from the user.

8. The electronic device of claim **1**, wherein the polymer upper layer extends horizontally away from the housing beyond a boundary of the electrode.

9. The electronic device of claim **1**, further comprising an upper adhesive layer positioned over the polymer upper layer.

10. The electronic device of claim **9**, wherein the upper adhesive layer is positioned above the electrode.

11. The electronic device of claim **10**, wherein the upper adhesive layer extends horizontally away from the housing beyond a boundary of the polymer upper layer.

12. The electronic device of claim **1**, wherein the lower adhesive layer extends at least partially below the housing.

13. The electronic device of claim **1**, wherein the lower adhesive layer does not extend below the housing.

* * * * *

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Kumar et al.

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(54) **DEVICE FEATURES AND DESIGN ELEMENTS FOR LONG-TERM ADHESION**

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CPC ***A61B 5/282*** (2021.01); ***A61B 5/25*** (2021.01); ***A61B 5/259*** (2021.01); ***A61B 5/291*** (2021.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 5/04; A61B 5/0408; A61B 5/04085; A61B 5/04087; A61B 5/0492;
(Continued)

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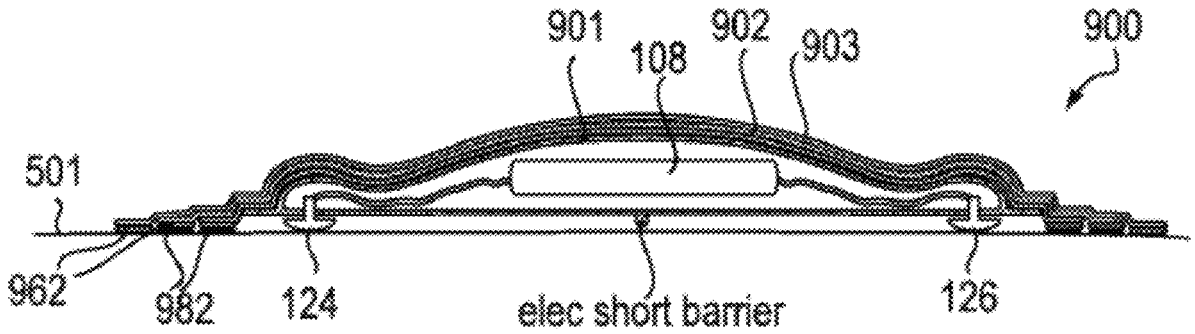
(57) **ABSTRACT**

An electronic device for long-term adhesion to a mammal includes a housing with an electronic component. The electronic device may include a first wing and a second wing, each being integrally formed with the housing. An electrode is positioned on a bottom surface of each of the wings, the electrodes electrically connected to the electronic component. An adhesive layer is provided for adhesion to a surface of the mammal. The adhesive layer may cover a portion of the bottom surfaces of the wings but generally does not cover the electrode or a bottom surface of the housing. A method of applying an electronic device to a mammal includes removing first and second adhesive covers
(Continued)



from first and second wings of the electronic device to expose an electrode and an adhesive coated on a bottom surface of each wing.

10 Claims, 11 Drawing Sheets

Related U.S. Application Data

continuation of application No. 16/723,208, filed on Dec. 20, 2019, now Pat. No. 11,141,091, which is a continuation of application No. 16/138,819, filed on Sep. 21, 2018, now Pat. No. 10,517,500, which is a continuation of application No. 15/005,854, filed on Jan. 25, 2016, now Pat. No. 10,405,799, which is a continuation of application No. 13/890,144, filed on May 8, 2013, now Pat. No. 9,241,649, which is a continuation of application No. 13/563,546, filed on Jul. 31, 2012, now Pat. No. 8,538,503, which is a continuation of application No. 13/106,750, filed on May 12, 2011, now Pat. No. 8,560,046.

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CPC A61B 5/0531; A61B 5/6801; A61B 5/6832–6833

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See application file for complete search history.

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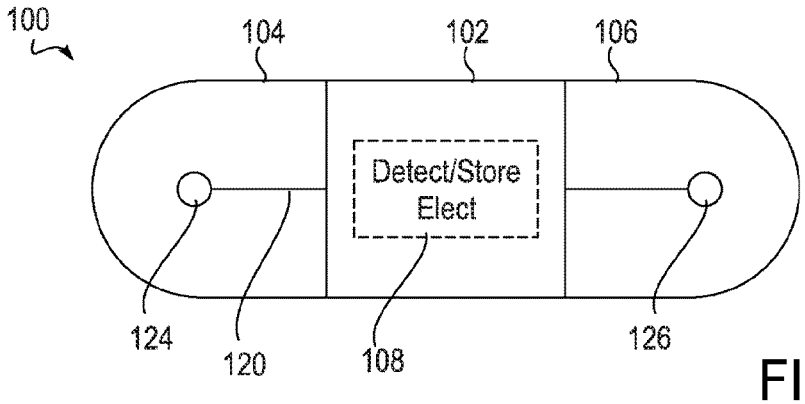
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Detect/Store
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FIG. 1

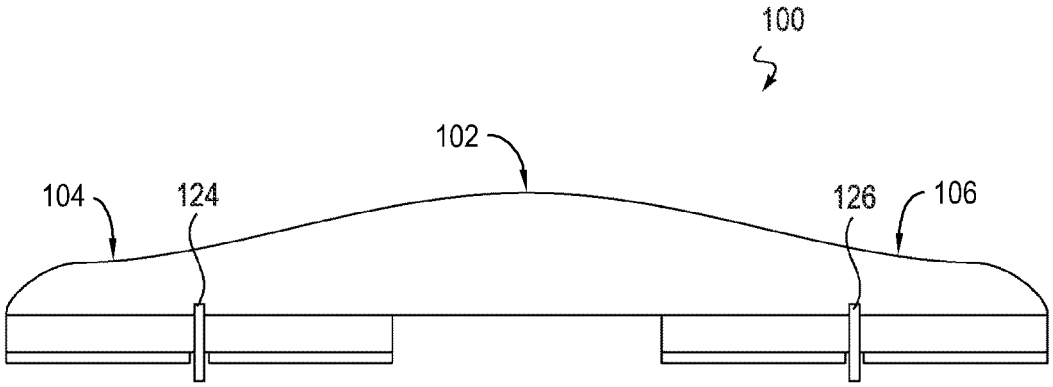
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FIG. 1A

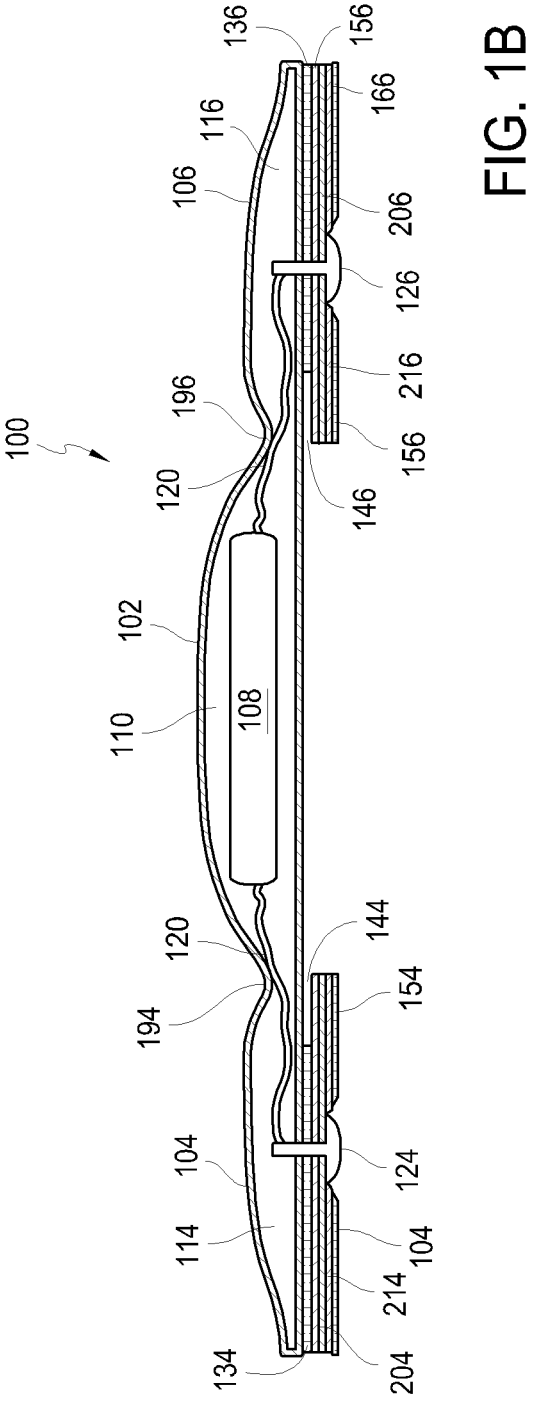
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FIG. 1B

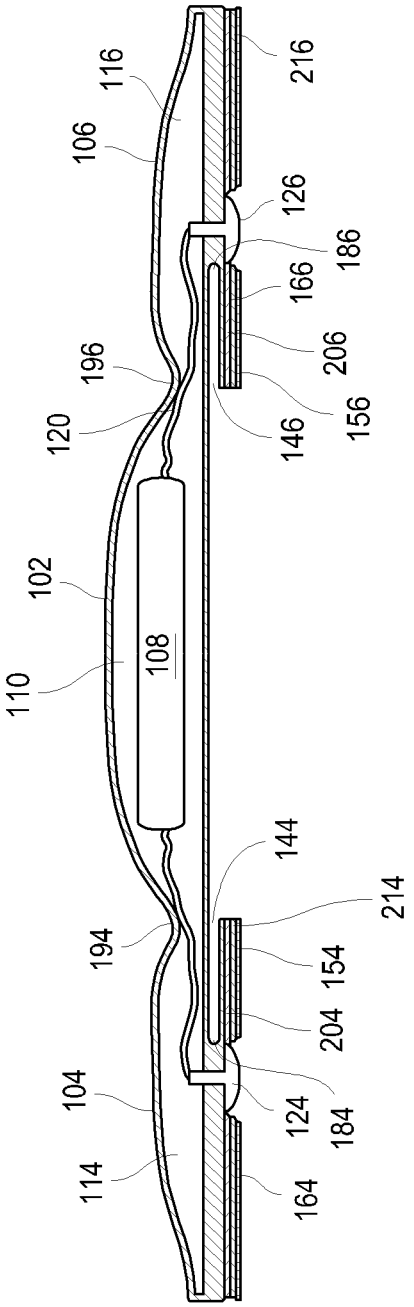
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FIG. 1C

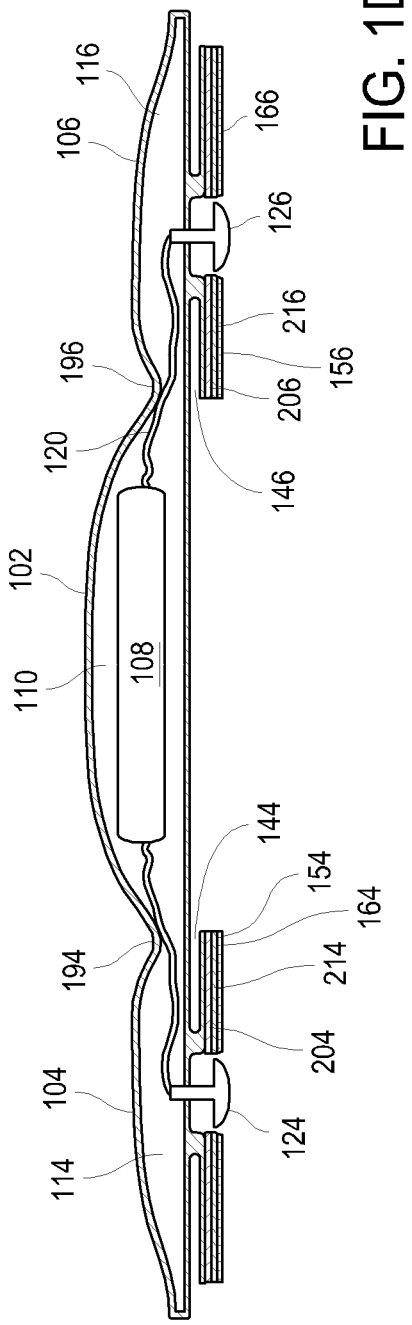
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FIG. 1D

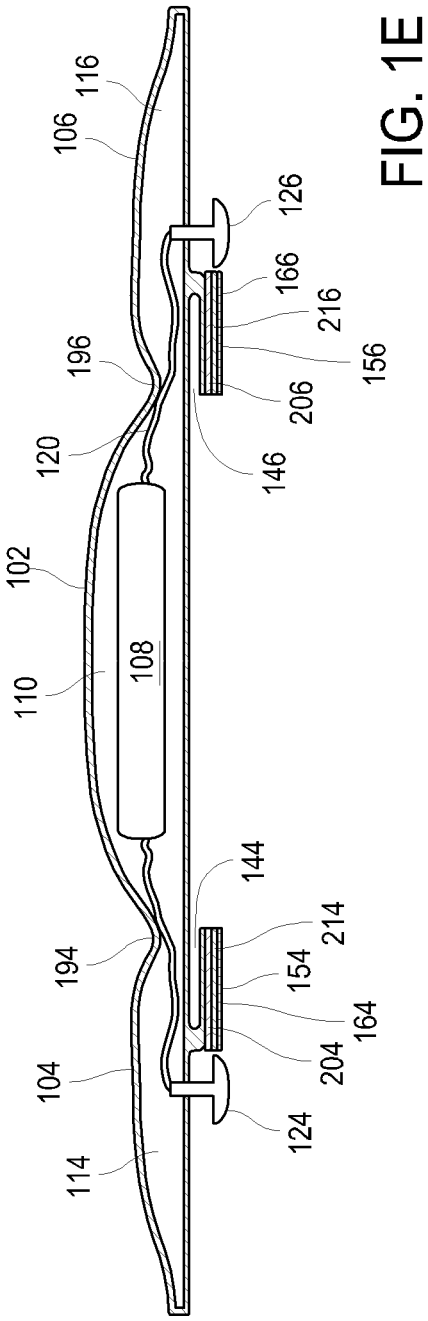
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FIG. 1E

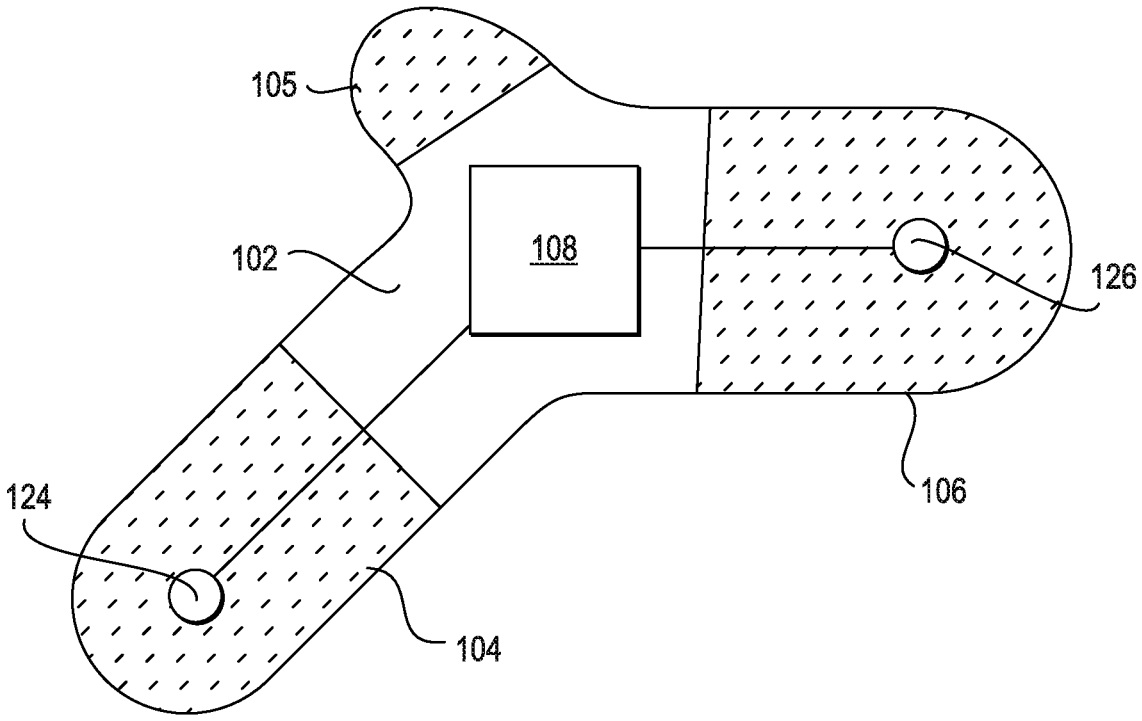

FIG. 1F

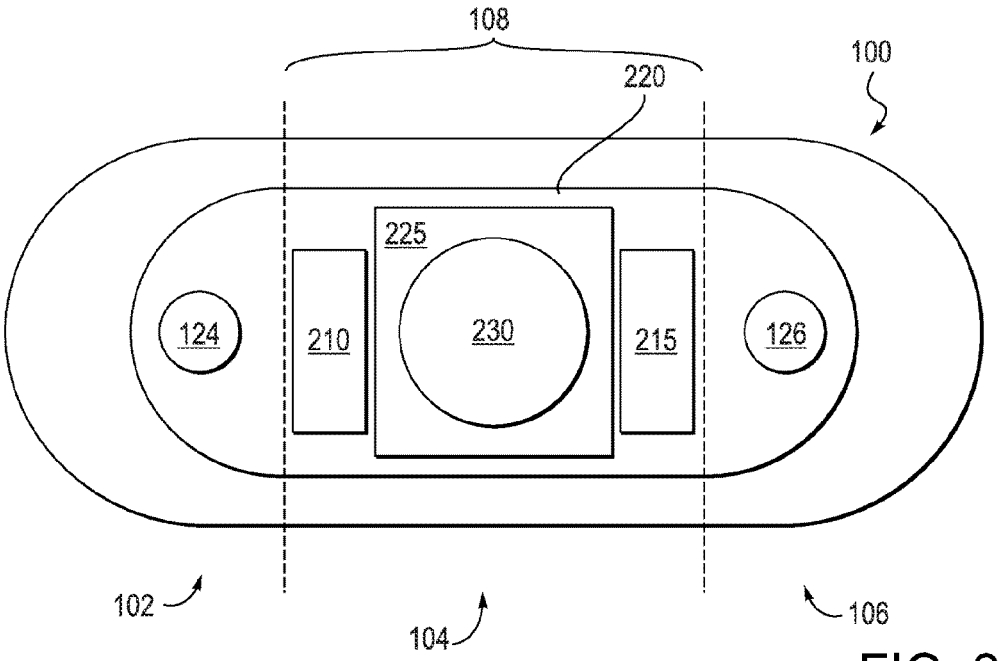

FIG. 2A

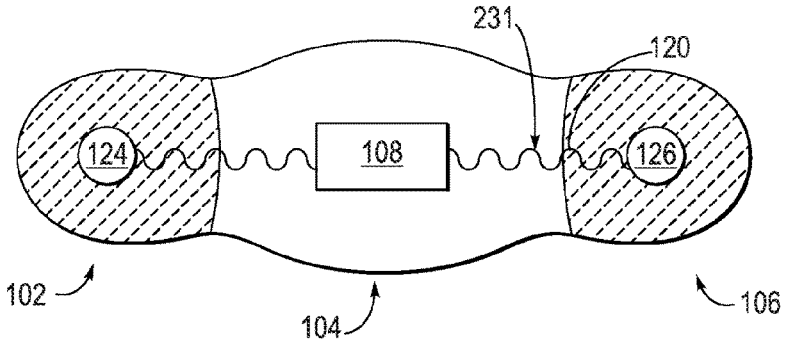

FIG. 2B

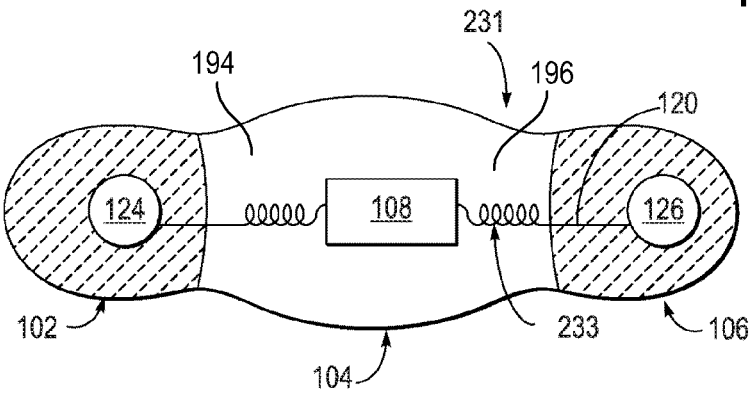

FIG. 2C

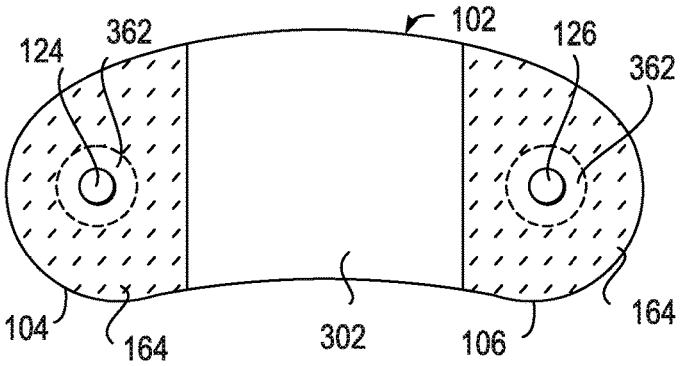

FIG. 3

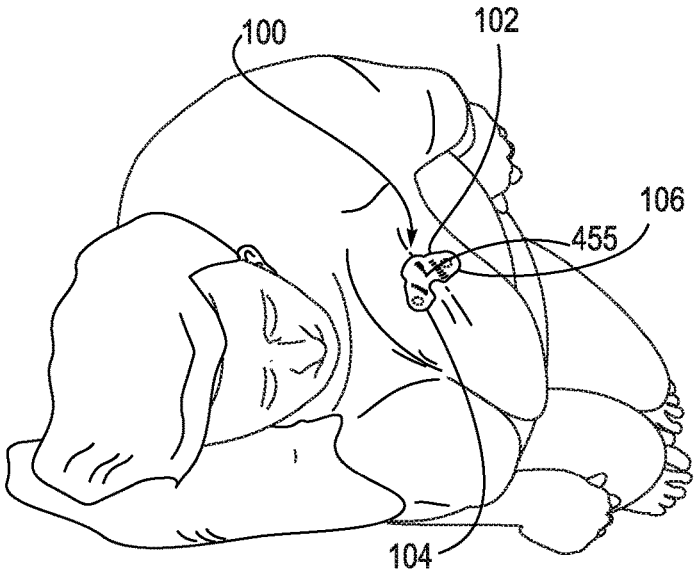

FIG. 4A

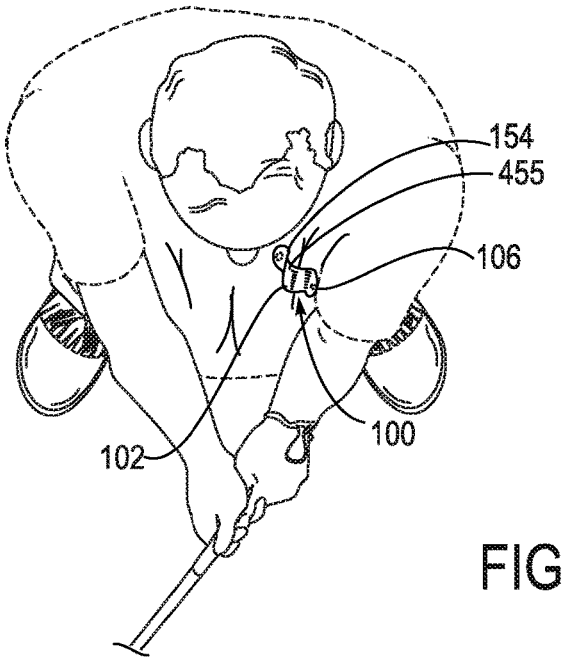

FIG. 4B

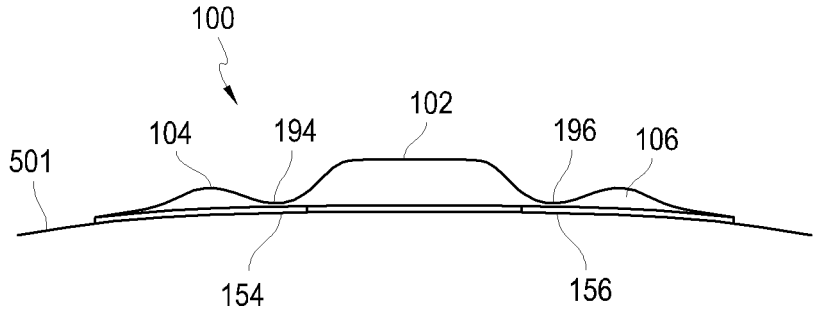

FIG. 5A

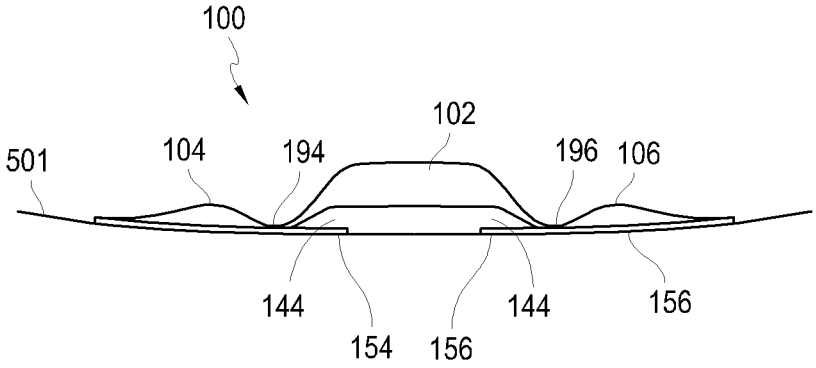

FIG. 5B

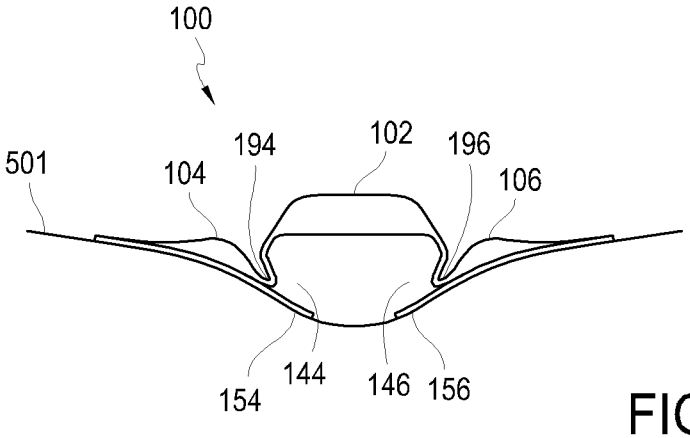

FIG. 5C

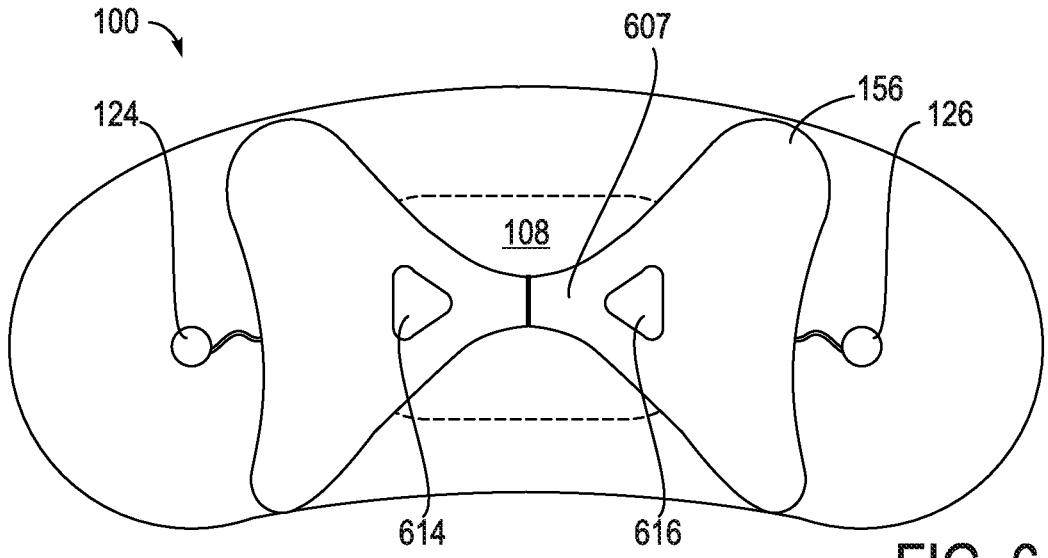

FIG. 6A

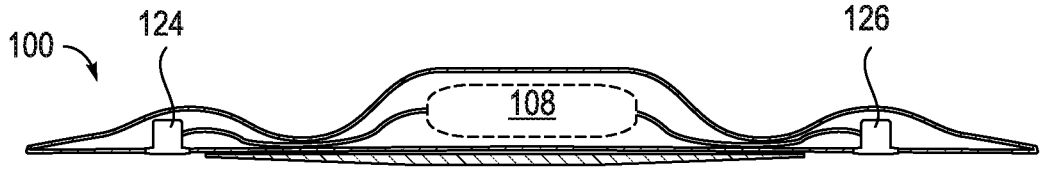

FIG. 6B

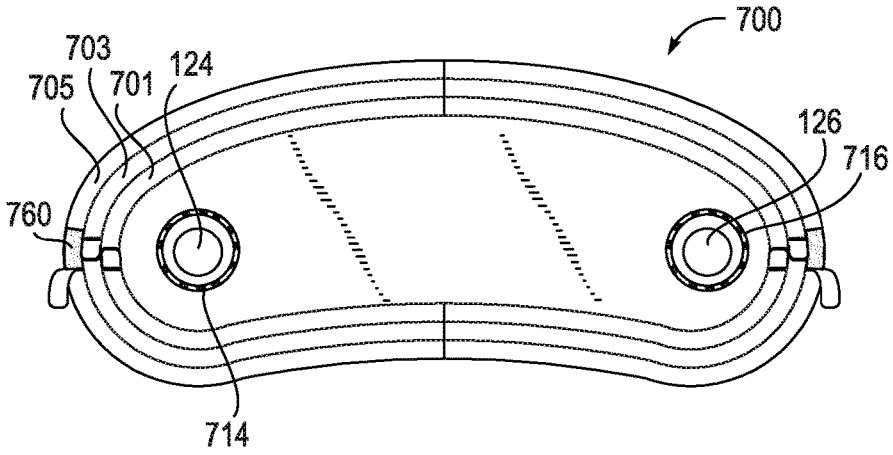

FIG. 7A

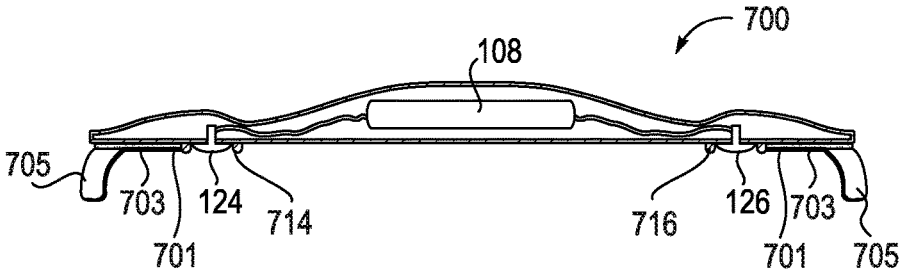

FIG. 7B

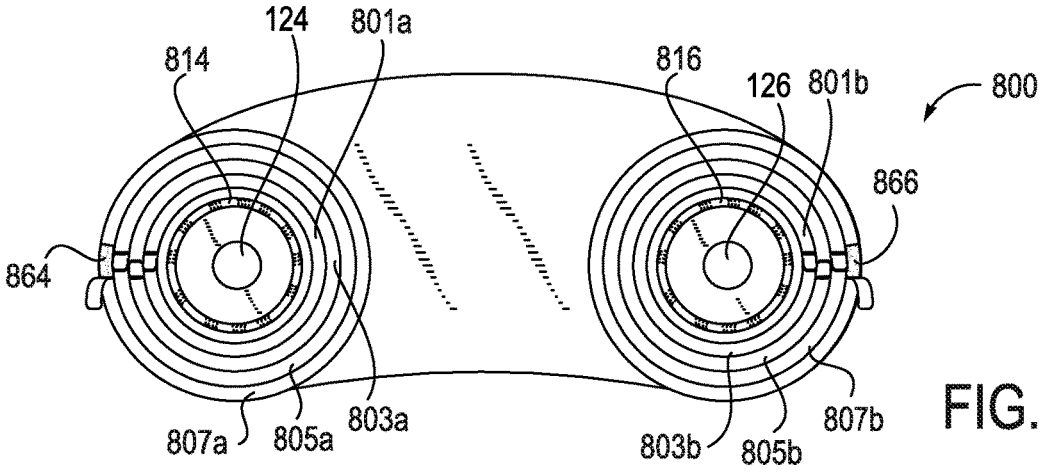

FIG. 8A

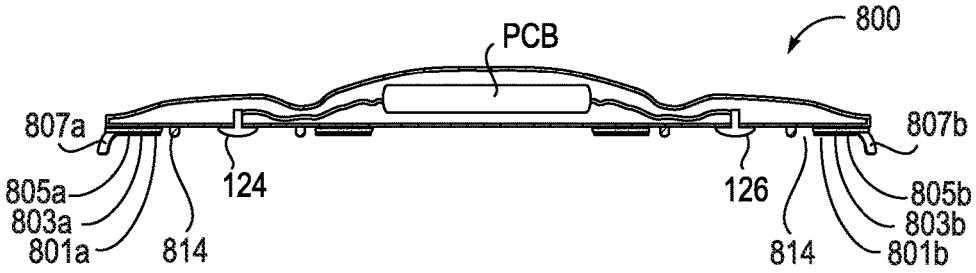

FIG. 8B

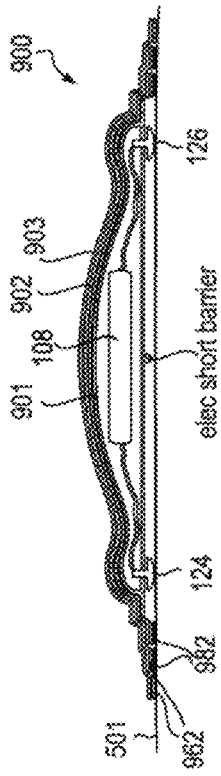

FIG. 9A

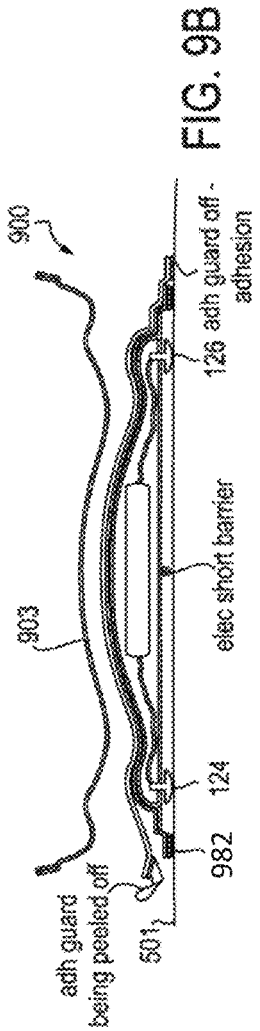

FIG. 9B

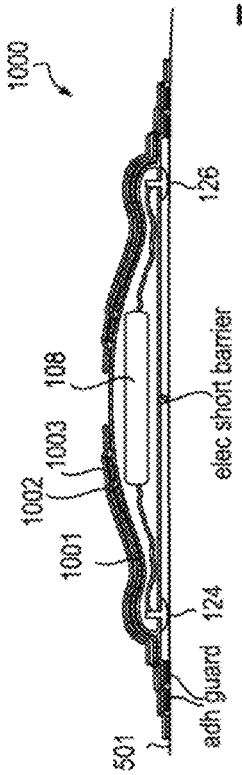

FIG. 10A

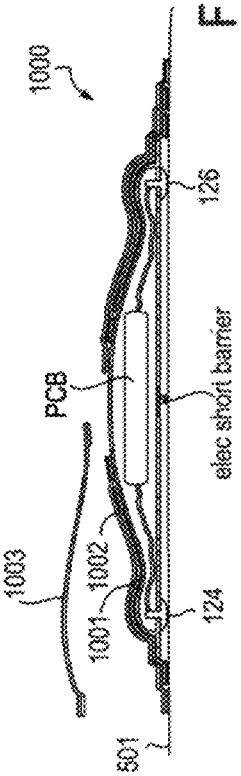

FIG. 10B

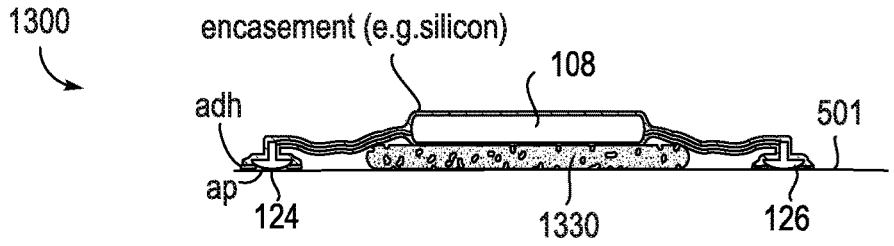

FIG. 11

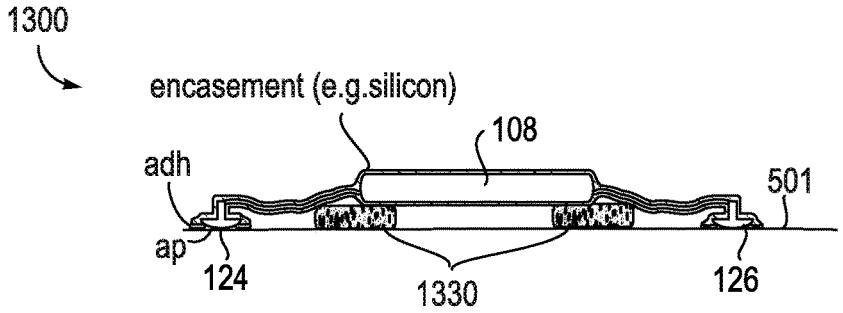

FIG. 12

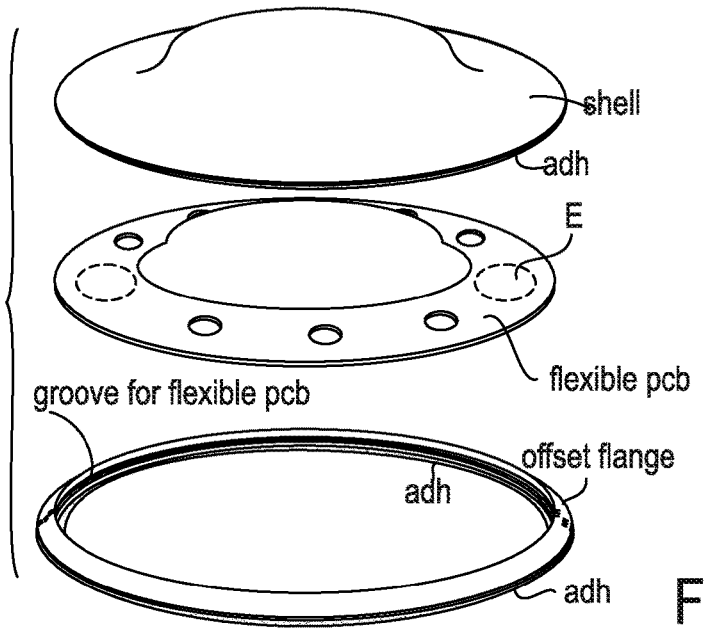

FIG. 13A

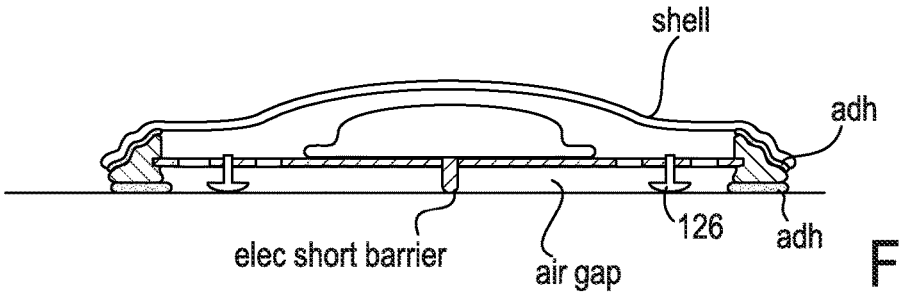

FIG. 13B

DEVICE FEATURES AND DESIGN ELEMENTS FOR LONG-TERM ADHESION

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 17/304,811, filed Jun. 25, 2021, titled "Device Features and Design Elements for Long-Term Adhesion" which claims priority to U.S. application Ser. No. 16/723,208, filed Dec. 20, 2019, titled "Device Features and Design Elements for Long-Term Adhesion" which claims priority to U.S. application Ser. No. 16/138,819, filed Sep. 21, 2018, titled "Device Features and Design Elements for Long-Term Adhesion" which claims priority to U.S. application Ser. No. 15/005,854, filed Jan. 25, 2016, titled "Device Features and Design Elements for Long-Term Adhesion" which claims priority to U.S. application Ser. No. 13/890,144, filed May 8, 2013, titled "Device Features and Design Elements for Long-Term Adhesion" which claims priority to U.S. application Ser. No. 13/563,546, filed Jul. 31, 2012, titled "Device Features and Design Elements for Long-Term Adhesion", which claims priority to U.S. patent application Ser. No. 13/106,750, filed May 12, 2011, which claims priority to U.S. Provisional Patent Application No. 61/334,081, filed May 12, 2010, entitled "Device Features and Design Elements for Long-Term Adhesion." All of the aforementioned applications are incorporated by reference as if fully set forth herein.

INCORPORATION BY REFERENCE

All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD OF THE INVENTION

This application relates to devices worn on a body for monitoring, recording, reporting and/or treating the person wearing the device. Improvements in the device design elements and functionality are disclosed for maintaining the device in contact with and operational for extended periods of time, typically longer than 24 hours.

BACKGROUND OF THE INVENTION

The ability to adhere a medical device to a human body for a long-period of time is dependent on a variety of factors. In addition to the type and nature of the adhesive chosen, another factor is the mechanical design of the device. By design, this refers to, but is not limited to, the device shape, size, weight, flexibility, and rigidity. These design elements are influenced by a number of additional factors, including, hut not limited to, where on the body the device will attach and the duration of the attachment, moisture conditions in that area, movement conditions in that area, stretching and contraction in that area, interactions with external factors in that area such as clothing, and purposeful and/or inadvertent interaction between the person wearing the device and the device.

As many are typically used on the body for less than 24 hours, devices have not been designed that can withstand longer-term adhesion. Hence, there is a need to implement device features and design elements that have the ability to enhance the likelihood of adhesion of a device to a human body for 24 hours or more, while accommodating the functionality, shape, size, weight, flexibility, and rigidity of a given device.

SUMMARY

In one aspect of the invention, there is an electronic device for long-term adhesion to a mammal. The device has a housing containing an electronic component with a first wing and a second wing integrally formed with the housing. There is an electrode positioned on a bottom surface of each of the wings with the electrodes electrically connected to the electronic component. An adhesive layer is provided tor adhesion to a surface of the mammal. The adhesive layer is coated on a portion of the bottom surface of the wings. The adhesive layer is not coated on the electrode or on a bottom surface of the housing.

The electronic component in any of the devices described herein may include a processor having a memory with computer readable instructions to record signals from the first and second electrodes while the electronic device is attached to the mammal. The processor may be configured to only convert signals from the electrodes to digital signals, filter those signals and then store the signals in memory.

In another aspect, the device includes a flap connected to each of the wings. The flaps may extend below the housing. Additionally or alternatively, the adhesive layer is coated on a bottom surface of the flaps.

In another aspect, the device includes a connector segment In one aspect, the connector segment configured to connect the flaps together. In other aspects, the connector segment is located at least partially below the housing. Still further, the connector segment is not attached to the housing.

In one alternative, the adhesive layer is coated on a bottom surface of the flap.

In still another aspect, the adhesive for adhesion to a surface of the mammal is an adhesive that can absorb fluids. In another aspect, the adhesive that can absorb fluids is a hydrocolloid adhesive. In another aspect, the adhesive for adhesion to a surface of the mammal is a pressure-sensitive adhesive. The pressure sensitive adhesive is selected from the group consisting of: a polyacrylate, a polyisobutylene, and a polysiloxane. In one alternative, the device includes a diffusion barrier between the adhesive layer and each of the wings. The device may also include an additional adhesive layer and material layer between the wing and the adhesive layer for adhesion to the mammal. The material layer is configured to prevent diffusion of adhesive components from the adhesive layer to the wing. The diffusion barrier may be made from polyester or other suitable synthetic material.

In one aspect of the device, all or substantially all of the electronic components are within the housing. In another aspect, the wing is free from electronic components. In one aspect, the wing is more flexible than the housing. In one alternative, the wings and the housing are made from the same material. In another aspect, the wings and the housing are made from different materials. In another, the wings are made from a fabric. In still another aspect, the material used to make the wings includes a synthetic fiber. In another alternative, the wing and the flap are composed of the same material.

In another alternative, the device includes a hinge portion between the housing wmg. The hinge portion is configured to allow the device to bend between the housing and the wmg. In one aspect, the hinge portion exists between a rigid

portion of the device and a flexible portion of the device. In one alternative, the rigid portion of the device corresponds to the portion of the housing including the electronics and the flexible portion of the device includes a wmg

In one aspect, the bottom surface of the wing and the bottom surface of the flap are contiguous. In another aspect, the bottom surfaces of the wings, the flap, and the connectors are contiguous. In still other aspects, the flaps and the connector are contiguous.

In another aspect, the connector has at least one hole extending it. The hole may have any of a number of shapes such as circular, oval, round, or triangular.

In one aspect, the housing is thicker at a center of the housing than at edges of the housing.

In another aspect of the device, the housing is unattached to the mammal when the electrodes are in contact with the mammal.

In another alternative aspect of a device for long-term adhesion to a mammal, the device includes a housing with a first wing extending laterally from the housing and a second wing extending laterally from the housing without overlapping the first wing, There is a first electrode positioned on a bottom surface of the first wing and a second electrode positioned on a bottom surface of the second wing. An electronic memory is positioned within the housing. The electronic memory is configured to receive and store electronic signals from the first and second electrodes while the electronic device is attached to the mammal. There is also an adhesive layer on a portion of a bottom surface of the first wing and the second wing. The adhesive is not on a bottom surface of the housing. When the device is worn on the mammal, only the adhesive layer(s) are attached to the mammal.

In one aspect, the portion of the bottom surface of the first wing and the second wing does not include the first and second electrodes. In one device aspect, the first wing, the second wing, and the housing are formed from the same material. In still another, the first wing, the second wing and the housing integrally form a monolithic structure. In other aspects, an angle formed by the first wing, the second wing, and the housing is between approximately 90° and 180°, In one variation, the angle is approximately 180°, In another variation, the angle is approximately 135°.

In still other embodiments, there is a first hinged portion between the first electrode and the processor and a second hinged portion between the second electrode and the housing.

In a further aspect, at least a portion of the body uncovered is not adhered to the mammal when signals from the electrodes are being recorded in memory.

In another aspect, the device includes a first flap connected to the first wing medial to the first electrode and a second flap connected to the second wing medial to the second electrode. Each nap may extend below the housing.

The device may also include a connector segment configured to connect the flaps together. In one aspect, the connector segment is located at least partially below the housing, but is not attached to the housing.

In another aspect, there is an electronic device that has a patch including a housing containing an electronic component. There is an electrode positioned on a bottom surface of the patch, the electrode electrically connected to the electronic component. There is a first adhesive strip extending around the perimeter of the patch and a second adhesive strip extending around the perimeter of the first adhesive strip. In one aspect, the first adhesive cover over the first adhesive strip and a second adhesive cover over the second adhesive strip. The first and second adhesive covers may be configured to be separably removed from the first and second adhesive strips. In one alternative, the first adhesive strip extends between the first and second adhesive covers. In another alternative, the adhesive in the first and the second adhesive strips is an adhesive that can absorb fluids. In still another aspect, the adhesive that can absorb fluids is a hydrocolloid adhesive. In one alternative, the adhesive in the first and the second adhesive is a pressure-sensitive adhesive. In some aspects, the pressure-sensitive adhesive is a polyacrylate, a polyisobutylene, or a polysiloxane.

In one alternative, the second adhesive strip partially overlaps the first adhesive strip. In another aspect, the second adhesive strip is attached to a shell, the shell overlapping the first adhesive strip.

In still another alternative device for long-term adhesion to a mammal, the device includes a patch having a housing with an electronic component contained therein, There is an electrode positioned on a bottom surface of the patch. The electrode electrically connected to the electronic component There is a porous foam pad configured to the positioned between the electronic component and the mammal. In one aspect, the porous foam pad comprises a biocompatible foam material. In one variation, the porous foam pad can absorb fluids. In still another aspect, the porous foam pad is attached to the housing. In another, the porous foam pad is configured to be attached to the mammal. In another request, the porous foam pad can absorb fluids.

In one aspect of a method of applying an electronic device, there is a step of removing a first adhesive cover from the first wing of the electronic device to expose an electrode and an adhesive coated on a bottom surface of a first wing, There is a step of placing the exposed electrode into contact with the mammal by adhering the adhesive coated bottom of the first wing to the mammal. There is also a step of removing a second adhesive cover from the second wing of the electronic device to expose an adhesive coated on a bottom surface of the second wing and another exposed electrode, There is also a step of placing the another exposed electrode into contact with the mammal by adhering the adhesive coated bottom of the second wing to the mammal. After performing the removing and the placing steps, the housing is unattached to the mammal, but is held in position on the mammal using the adhesive coated bottoms of the first and the second wings.

In one alternative method of attaching a device, the electronic device includes a first nap connected to the first wing and a second flap connected to the second wing. The first and second flaps each extend below the housing. The step of removing a first adhesive cover from the first wing may also include exposing an adhesive coated on a bottom surface of the first flap. The step of removing a second adhesive cover from the second wing may also include exposing an adhesive coated on a bottom surface of the second flap.

In another alternative method of attaching a device, after performing the removing and the placing steps, the housing is held in position on the mammal using only the adhesive coated bottoms of the first wing, the second wing, the first flap and the second flap.

In an alternative aspect of a method of applying an electronic device to a mammal for long-term adhesion, the method includes removing a first adhesive cover from the first wing of the electronic device to expose an electrode and an adhesive coated on a bottom surface of the first wing. There is also a step of removing a second adhesive cover from the second wing of the electronic device to expose an

adhesive coated on a bottom surface of the second wing and another exposed electrode. There is a step of placing the exposed electrodes into contact with the mammal by adhering the adhesive coated on the bottom of the first and the second wings to the mammal, After performing the removing and the placing steps, the housing is unattached to the mammal, but is held in position on the mammal using the adhesive coated bottoms of the first and the second wings.

There is also provided a method of applying an electronic device to a mammal for long-term adhesion wherein the electronic device includes a patch. The patch includes an electronic component along with an electrode positioned on a bottom surface of the patch and electrically connected to the electronic component. There is a first adhesive strip extending around the perimeter of the patch and a second adhesive extending around the perimeter of the first adhesive strip. One aspect of a method of applying the device includes a step of removing an adhesive cover from the second adhesive strip of the electronic device. There is a step of applying pressure to the second adhesive strip to adhere the second adhesive strip to the mammal such that the electrode is in contact with the mammal. Then, after a period of time, removing an adhesive cover from the first adhesive strip of the electronic device. Next, there is the step of applying pressure to the first adhesive strip to adhere the first adhesive strip to the mammal such that the electrode remains in contact with the mammal.

In another alternative method of applying an electronic device to a mammal for long-term adhesion, the electronic device includes a patch, an electronic component, and an electrode positioned on a bottom surface of the patch and electrically connected to the electronic component. There is a first adhesive strip extending around the perimeter of the patch. The method includes a step of applying pressure to a first adhesive strip to adhere the first adhesive strip to the mammal such that the electrode is in contact with the mammal. After a period of time, placing a second adhesive strip around the perimeter of the first adhesive strip. Then there is the step of applying pressure to the second adhesive strip to adhere the second adhesive strip to the mammal such that the electrode remains in contact with the mammal.

Any of the above described devices may include additional aspects. A device may also include a first wire connecting the first electrode and the processor or an electronic memory and a second wire connecting the second electrode and the processor or an electronic memory. The first and second wires extend within the body and the first and second wings. In one aspect, the first and second wires extend within and are completely encapsulated within the body and the first and second wings. In one aspect, a conduit is provided within the body and the wings and the wires pass through the conduit. In one alternative, the conduit extends from the processor or electronic memory to an electrode so that the wire is completely within the conduit. In still other aspects of the devices described above, the first and second wires connecting the electrodes to the processor or electronics each include slack between the electrode and the processor. In one aspect, the slack is located in a portion of each wing that is configured to bed or flex. In another aspect, the slack is a portion of the wire within the wing and at least partially coiled about the first or the second electrode. In still other aspects, the slack is provided by a portion of the wire formed into a coil, a wave pattern, or a sinusoidal pattern along its length the connection point on the electronics to the connection point on the electrode.

In still other alternatives, the devices described above may be applied to any of a wide variety of conventional physiological data monitoring, recording and/or transmitting devices. Any of the improved adhesion design features and aspects may also be applied to conventional devices useful in the electronically controlled and/or time released delivery of pharmacological agents or blood testing, such as glucose monitors or other blood testing devices. Additional alternatives to the devices described may include the specific components of a particular application such as electronics, antenna, power supplies or charging connections, data ports or connections for downloading or off loading information from the device, adding or offloading fluids from the device, monitoring or sensing elements such as electrodes, probes or sensors or any other component or components needed in the device specific function. In still other aspects, the electronic component in any of the above devices is an electronic system configured for performing, with the electronic signals of the mammal detected by the electrodes, one or more or any combination of or the following electronic functions: monitoring, recording, analyzing, or processing using one or more algorithms electronic signals from the mammal. Still further, any of the devices described above may include appropriate components such that the device is used to detect, record, process or transmit signals or information related to signals generated by a mammal to which the device is attached including but not limited to signals generated by one or more of EKG, EEG and/or EMG.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. **1** is a top view of a patch having two wings;

FIG. **1**A is a representative cross-section of an embodiment of the patch in FIG. **1**;

FIG. **1**B is a representative cross-section of another embodiment of the patch in FIG. **1**;

FIG. **1**C is a representative cross-section of another embodiment of the patch in FIG. **1**;

FIG. **1**D is a representative cross-section of another embodiment of the patch in FIG. **1**;

FIG. **1**E is a representative cross-section of another embodiment of the patch in FIG. **1**;

FIG. **1**F is a top view of a patch having three wings illustrating an alternative electrode-electronics-electrode orientation;

FIG. **2**A is a schematic drawing of the electronics contained within a patch;

FIG. **2**B is a schematic drawing of a patch with wiring having slack in the form of undulations between electronics and electrodes;

FIG. **2**C is a schematic drawing of a patch with wiring having slack in the form of a coil between electronics and electrodes;

FIG. **3** is the bottom view of a patch having adhesive thereon;

FIG. **4**A shows a patch as worn by a person rolled to the side;

FIG. **4**B shows a patch as worn by a person playing golf;

FIG. **5**A shows a patch in response to a concave bend of the skin;

FIGS. **5**B and **5**C show a patch in response to a convex bend of the skin;

FIG. **6**A is a bottom view of a patch having a connector between two flaps;

FIG. **6**B is a cross-section of the patch of FIG. **6**A;

FIG. **7**A is a bottom view of a patch having multiple covers forming strips of adhesive;

FIG. **7**B is a cross-section of the patch of FIG. **7**A;

FIG. **8**A is a bottom view of a patching having multiple covers forming strip of adhesive around each electrode;

FIG. **8**B is a cross-section of the patch of FIG. **8**A;

FIGS. **9**A and **9**B show a patch having multiple layers formed thereon;

FIGS. **10**A and **10**B show a patching having multiple layers formed thereon, each layer having multiple patches of adhesive;

FIG. **11** shows a patch having an open cell support;

FIG. **12** shows a patch having an annular open cell support;

FIG. **13**A shows a patch having a protective shell thereon; and

FIG. **13**B shows a cross-section of the patch of FIG. **13**A.

DETAILED DESCRIPTION

The following device features and design elements can be implemented into any device being adhered to the human body for a long-period of time, typically greater than 24 hours. As an example, the following device features and design elements can be used for long-term adhesion of a cardiac rhythm monitoring patch ("patch") to the chest of a person.

Referring to FIGS. **1** and **1**A, a patch **100** for long term adhesion includes a housing **102**. The housing **102** can be formed from any flexible, durable material, such as a biocompatible polymer, for example silicone. The housing **102** can include electronic components **108** therein. As shown in FIG. **2**, the electronics **108** can include a printed circuit board **220**, a battery **225**, and a communications port mounted on the printed circuit board **220**. The printed circuit board **220** can include analog circuits **210**, digital circuits **215**, and an activation or event notation button or switch **130**. The electronics **108** can be used, for example, to record continuous physiological signals from a mammal wearing the patch **100**. A system for continuously recording data is described further in co-owned U.S. application Ser. No. 11/703,428, filed Feb. 6, 2007, the entire contents of which are incorporated by reference herein.

As shown in FIGS. **1** and **1**A, wings **104**, **106** can be connected to the housing **102**. The wings **104**, **106** can be integral with the housing **102** and, in some embodiments, can be formed of the same material as the housing **102**. The wings **104**, **106** can be more flexible than the electronic components **108**, which can be substantially rigid. An electrode **124**, **126** can extend through a bottom surface of each wing **104**, **106**. The electrodes can be positioned to detect an ECG of a mammal wearing the patch **100** for processing by the electronics **108**. For example, the electrodes can be more than 2 cm apart, such as more than 3 cm apart, for example at least 6 cm apart. The electrodes **124**, **126** can be integral with the wings **104**, **106** so as to be inseparable from the wings **104**, **106** when the patch is in use.

For a patch **100** that is entirely flexible and can conform, stretch, and adapt to the movement and conditions of the chest underneath the device, adhesive can be placed over the entire surface of the device that is in contact with the body, except for areas where sensors, electronics, or others elements such as electrodes are interacting with the body related to the functioning of the device may be incorporated. Thus, as shown in FIG. **3**, an adhesive layer **166** can coat the bottom of the patch **100** tor attachment to the skin. For a patch **100** in which there may be some areas that are not completely flexible and may not be able to stretch or contract (e.g., the electronics **1**(**8**), adhesive may be excluded from the portion of the patch **100** underneath these areas. Thus, for example, the bottom surface **302** of the housing **102**, which contains the electronics, can remain free from adhesive. As shown in FIG. **1**A, by not coating adhesive on a bottom surface of the housing **102**, the housing **102** can float above the adhered portions, allowing for increased flexibility of the patch, as will be discussed further below. Further, as shown in FIG. **3** the bottom surface of the electrodes **124**, **126** can remain free of adhesive. For example, a ring **362** without adhesive can be formed around each electrode **124**, **126** to separate the electrodes from the adhesive **164**, The adhesive can be, for example, a pressure-sensitive adhesive, such as polyacrylate, polyisobutylene, or a polysiloxane. Alternatively, the adhesive can be a hydrocolloid which advantageously absorbs water.

The wings **104**, **106** and the housing **102** can form a smooth, contiguous outer surface to the patch **100**, As shown in FIG. **1**A, when viewed from the top, the housing **102** and wings **104**, **106** can together form an oblong substantially oval shape. Further, the housing **102** can have a thickness that is greater than the thickness of the wings **104**, **106**. The housing **102** and each of the wings **104**, **106** when viewed in profile, can each form a dome with a height that is greater at the center than at the ends of the respective component, i.e. some or all of the components can be tapered at the ends and/or sides.

The electronics **108** can extend along only a portion of the distance between the electrodes **104**, **106**. For example, the electronics can occupy less than 90% of the distance between the electrodes, for example less than 80%. By having the electronics **108** in a relatively limited space between the electrodes **124**, **126**, the flexibility of the patch **100** can be increased

The housing **102** can provide a watertight enclosure **110** for electronic components **108** of the patch **100**, The electronics **108** can be unattached to the housing **102** such that the electronics **108** are free to move within the watertight enclosure **110**. Allowing the relatively rigid electronics **108** to move freely within the flexible housing **102** advantageously enhances the overall flexibility of the patch **100**, The wings **104**, **106** can each have a watertight enclosure **114**, **116** formed therein, which can be contiguous with the watertight enclosure **110** of the housing **102**.

Wiring **120** or other suitable electrical connections can connect the electrodes **124**, **126** with the electrical components **108** of the housing. In some embodiments, as shown in FIGS. **1**B-**1**E, the contiguous nature of the enclosure **110** and the enclosures **114**, **116** allows the wiring **120** to extend within the patch **100** from the electrodes **124**, **126** to the electronic components **108**. In other embodiments, one or more channels, tubes, or conduits are provided between the housing **102** and the wings **104**, **106**, to provide space for the wiring **120**. The tube or channel may be straight or curved. In use, the wire **120** positioned in the enclosures **110**, **114**, **116** or in the tube or channel may move relative thereto in order to remain flexible within the housing. In one aspect, the flexible channels or tubes are formed within the device housing so that the housing, as it is being stretched, does not affect the ability of the components, such as wires, that may connect more rigid structures, to move or elongate.

As shown in FIG. **1**, the wire **120** is straight with a direct line of connection between the electrodes **124**, **126** and the

electronics **108**. FIG. **1** illustrates an embodiment where the length of the wires **120** connecting the electrodes **124**, **126** to electronics **108** are about the same distance as the spacing between the electrode connection point on electronics **108** and the electrodes **124**, **126**. FIG. **1**F also illustrates a straight line type connection where wire **120** length is nearly the same as the spacing between the electronics **108** and the electrodes **124**, **126**. However, as a patient moves, the patch **100** flexes along with patient movement. As shown in FIGS. **4**B and **5**C, patch flexion may be severe and is likely to occur during long term monitoring. In order to address the possible dislocation or breakage of the wire **120**, the length or shape of the wire **120** may be selected to permit patch flexion to occur with little risk of wire **120** pulling from the electrode or electronics. Numerous alternatives are possible to compensate for patch flexion. Exemplary confirmations include undulations or zig-zags **231** as shown in FIG. **2**B, coils **233** as shown in FIG. **2***c*, or a configuration that partially or fully wraps around an electrode. In some embodiments, other components, such as the circuit hoard or electrodes, can alternatively or additionally contain additional length to help accommodate stretch or displacement. When the patch **100** is attached to a mammal, the slack in the wiring **120** allows the patch **100** to flex while not placing stress on the wiring **120**.

While the illustrated embodiments of FIGS. **1**A-**1**D show only two wings and show the electrodes and electronics in a direct line in a approximate 180 degree alignment of electrode **124** to electronics **108** to electrode **126**), other configurations are possible. For example, as shown in FIG. **1**F, the wings **104**, **106** are arranged in an orientation less than 180 degrees. In the illustrated embodiment, the angle formed by the electrodes and the electronics is about 135 degrees. Other ranges are possible so long as electrode spacing is provided to permit ECG monitoring. The orientation of the wings **104**, **106** to the housing **102** also illustrates the use of an additional adhesive tab **105**. Tab **105** is shown as a semicircular extension of the body **102**. The bottom of tab **105** can include adhesives as described herein and is used to provide additional anchoring of the patch to the patient. The tab **105** may be formed in any of a number of different shapes such as rectangles, ovals, loops or strips. Further, in some embodiments, the tab **105** can function similar to a wing, e.g., include an electrode therethrough that connects to the electronics **108**.

Referring to FIGS. **1**A-**1**D and **2**B-**2**C, a hinge portion **194**, **196** in the patch **100** can extend between each electrode **124**, **126** and the electronics **108**. The hinge portions **194**, **196** can have a thickness less than the thickness of surrounding portions of the patch **100**, For example, if the hinge portions **194**, **196** are in the wings **104**, **106**, then the thickness can be less than adjacent portions of the wings. Likewise, the hinge portions **194**, **196** can have a width less than adjacent portions of the patch **100**, e.g., less than adjacent portions of the wings **104**, **106**. Alternatively, the hinged portion can be formed by the adjunct between a rigid portion, i.e. the electronics **108**, and a more flexible portion. The hinged portion allows the patch **100** to bend between the housing **102** and wings **104**, **106** to compensate for any movement caused by the patient. As shown in FIGS. **2**B and **2**C, the slack in the wiring **120** can be placed at or proximal to the hinge portions **194**, **196** to allow for bending at the hinge portions **194**, **196** without pulling or breaking the wiring **120**.

Referring to FIGS. **4**A and **4**B, having adhesive on the bottom of the patch **100** except in the areas substantially around the electrodes and directly underneath the housing **102** can create a floating section **455** over the skin of the mammal to which the patch **100** is attached. The floating section **455** can house the more rigid or less flexible electronic components while the flexible wings **104**, **106** can be adhered to the skin and provide the flexibility necessary to hold the patch **100** in place. As a result of this selective use of adhesive areas and non-adhesive areas, the limitation on device flexibility imposed by the less flexible floating section can be mitigated or reduced by hounding the floating section with one or more adhered flexible areas. The flexible sections can thus adhere to the body if the underlying portion of the body is stretched and/or contracted while the floating section is free to move above the skin, for example if the person wearing the device rolls over (as shown in FIG. **4**A) or is involved in activities that can otherwise cause movement of the skin (as shown in FIG. **4**B).

Referring back to FIGS. **1**B-**1**E, each wing **104**, **106** can include a material layer **214**, **216** between the adhesive **164**, **166** and the wings **104**, **106**, The material layer **214**, **216** can be, for example, a polyester layer. The material layer **214**, **216** can be attached to the patch **100** with a layer of adhesive **204**, **206**, The adhesive **204**, **206** can be the same as the adhesive **164**, **166** or different. For example, the adhesive **204**, **206** could be a silicone adhesive. The material layer **214** can serve as a barrier to prevent diffusion or migration of adhesive components, such as a tackifier, from the adhesive **164**, **166** into the wings **104**, **106** or housing **102**. The material layer **214** can thus advantageously serve to maintain the strength of the adhesive **104**, **106** over time.

Referring still to FIGS. **1**B-**1**E, the patch **100** can further include a first flap **154** connected to the first wing **104** and a second flap **156** connected to the second wing **106**. The flaps **154**, **156** can both extend from a position on the wings **104**, **106** medial to the electrodes to a position below the housing **102**, such as below the electronics **108**. The flaps **154**, **156** can remain unattached to the housing **102**. As a result, gaps **144**, **146** can be formed between the flaps **154**, **156** and the housing **102**. The gaps can provide additional "floating" for the housing **102** and the relatively rigid components **108** contained therein.

In some embodiments, shown in FIG. **1**B, the flaps **154**, **156** can be attached to the wings **104**, **106** with adhesive **134**, **136**. The adhesive **134**, **136** can be the same as the adhesive **164**, **166** or different. For example, the adhesive **134**, **136** could be a silicone adhesive. In other embodiments, shown in FIGS. **1**C-**1**E, the flaps **154**, **156** can be integral with the wings **104**, **106**. For example, the flaps **154**, **156** can be solvent welded to and/or formed during the molding process of the wings **104**, **105** such that hinges **194**, **196** form below the wings **104**, **106**. Additionally or alternatively, one or more of the flaps **154**, **156** may be separably attached to the wings **104**, **106**. In some embodiments, shown in FIGS. **1**B and **1**C, the materials making up the flaps **154**, **156** can extend all the way to the lateral edge of the patch **100**. In other embodiments, shown in FIG. **1**D, a flap can extend on each side of the electrodes, i.e. one flap can extend medially and the other laterally. In some embodiments, the lateral and medial—extending flaps are part of the same annular flap. In other embodiments, shown in FIG. **1**E, the flaps and materials making up the flaps extend only from a position medial to the electrodes underneath the housing.

The Flaps **154**, **156** may be positioned in virtually any relationship to the adhered flexible area such that, when attached in use, the attachment of the flap or flaps effectively counteracts the expected external forces acting on the device, specifically those forces that may dislodge the adhered flexible areas. Further, in embodiments such as that

shown in FIG. **1**F where there are more than two wings, there can be a flap corresponding to each additional wing.

The adhesive layers **164**, **166** can coat all or a portion of the bottom of each of the flaps **154**, **156**. In some embodiments, the adhesive **164**, **166** extends continuously from the bottom surface of the wings **104**, **106** to the bottom surface of the flaps **154**, **156**, except for areas proximate to the electrodes **124**, **126**. Further, the top surface of the flaps **154**, **156**, i.e. the surface closest to the housing **102**, can remain free of adhesive to ensure that the housing **102** remains floating. In some embodiments, the only portion of the patch **100** including adhesive for adhesion to the skin can be the flaps **154**, **156**.

Referring to FIGS. **5**A-**5**C, the naps **154**, **156**, can provide hinge-like behavior for the patch **100**, Thus, as shown in FIG. **5**A, if the skin **501** is stretched or bent in a concave manner, the gaps **144**, **146** between the flaps **154**, **156** and the housing **102** can approach zero such that the patch **100** can sit substantially flat on the skin **501**. As shown, the hinge portions **194**, **196** between the housing **102** and wings **104**, **106** can provide additional flexibility for concave bends by flattening as the patch **100** is stretched. In contrast, as shown in FIGS. **5**B and **5**C, as the skin **501** is bent in an increasingly convex manner, the gaps **144**, **146** between the flaps **154**, **156** and the housing **102** can increase, thereby allowing the flexible wings **104**, **106** to remain adhered to the skin and the rigid housing **102** to float above skin. As shown, the hinge portions **194**, **196** between the housing and the wings **104**, **106** can provide additional flexibility for convex bends by folding inward as the patch **100** is bent.

When placed substantially flat on the skin **501**, the patch **100** can have a height that extends no more than 2 cm off of the skin, such as no more than 1.5 cm off of the skin, when lying flat on the patient and no more than 4 cm, such as no more than cm off of the skin when floating above the skin. The relatively low height of the patch **100** can enhance long-term adhesion by reducing the potential for the patch **100** to snag or rip off of the skin.

Advantageously, the flaps **154**, **156** can function as anchors for adhesion that mitigates shear force. The flaps **154**, **156** can provide a different direction for the acute and chronic forces being experienced by the device due to stretching, contraction, or torsion to be spread out over both the flap as well as the flexible adhesive areas. Further, by pre-aligning the orientation of the floating section, adhered flexible area and the flaps, the device may be better able to tolerate (i.e., remain attached to the body and in use) and/or tailor the interaction with the forces acting on the device in order to better withstand the acute or chronic forces being experienced by the device. Tailoring the response of the device to the expected forces is one

Because the flaps can be used to counteract forces acting on a particular device, it is to be appreciated that the dimensions, flexibility, attachment technique, and/or orientation between a flap and another component may vary depending upon the purpose of a particular flap. Accordingly, a flap may have the same or different characteristics from another flap or component of the device. In one aspect, at least one flap is more flexible that the other flaps in a particular device. In another aspect, each of the flaps has similar flexibility. In still another aspect, at least one flap is more flexible than the device component to which it is attached or from which it originates. In still another aspect, at least one flap is less flexible than the device component to which it is attached or from which it originates.

Referring to FIGS. **6**A and **6**B, in one embodiment, the flaps **154**, **156** may be augmented by a connector segment **607** used to join the flaps together. The connector segment **607** can extend below the housing **102**, but remain unattached to the housing **102**. As shown in FIG. **6**A, the flaps **154**, **156** and the connector **607** can together form a butterfly shape. In one embodiment, the connector segment **607** and the flaps **154**, **156** are formed from a single piece of material. The connector segment **607** can be made of the same material as the flaps **154**, **156** or of different material. In one embodiment, the bottom surface of the connector is covered with adhesive. In another embodiment, the bottom surface of the connector does not include any adhesive. Further, as shown in FIG. **6**B, the connector segment **607** can be thicker in the middle, under the housing **102**, than near the edges, i.e., closer to the electrodes. The variable thickness can help prevent the connector segment **607** from capturing moisture thereunder. The connector segment **607** can advantageously prevent the device from flipping when attached to the patient

The connector segment **607** can include one or more holes **614**, **616**. In some configurations, the connector segment may trap moisture and/or inadvertently stick to the body. The holes **614**, **616** can advantageously minimize the potential for undesired sticking or moisture collection. The size, shape and placement of the holes mitigate or reduce the collection of moisture and/or undesired adhesive still providing a connector with sufficient structural integrity (i.e. the connector allows the flaps to be connected to one another in order to prevent them from folding). Additionally or alternatively, the connector holes could also be made to preferentially allow forces to be distributed along certain axes of the connector in order to further maximize the ability of the device to adhere tong-term in the face of significant acute and chronic forces due to stretching, contraction, and torsion.

Adhesive can be selectively applied to the connector and/or naps to provide the desired body attachment locations depending upon the specific use of the device. For example, one piece of material including flaps and the connector can be adhered along two or more edges and/or with adhesive only covering certain areas. In another aspect, at least a portion of the skin-contacting surface of the unitary nap connector structure does not include any adhesive. Additionally or alternatively, the connector segment incorporating the flaps may be integral parts of the larger device housing (e.g. could be molded as part of the device housing or enclosure).

In some embodiments, the patch **100** can include one or more release liners to cover parts of the adhesive prior to adhesion. As is particular to devices having multiple adhesive areas and/or multiple adhesive components (i.e., flaps and flexible sections), the manner of applying the device may be specifically detailed in order to ensure that the device and the adhesive portions are properly engaged. In one particular aspect, the release liners are removed in a particular order to minimize the likelihood that the device adhesive is misapplied. For example, a portion of the adhesive may be exposed first and used to affix the device to the body, Thereafter, a second set of adhesive liners may be removed to expose and affix one or more flaps to the body, A stepwise adhesive exposure method may be implemented during device application such that elements, such as the one or more flaps do not fold on themselves, for example.

Breaking up the areas in which the adhesive is used to adhere the device, whether it be splitting it up to rigid areas, to create flaps, to create connector segments with holes, of any of the other techniques described above may also have benefits in terms of preventing moisture bridges that could act as conducting pathways between electrical sensing ele-

ments, such as electrodes. Bridges of moisture could short-circuit electrical connections and/or prevent the proper functioning of the device, particularly if the device has an electrical function, such as sensing via electrodes.

In some applications, a long-duration patch may experience excessive forces due to acute (quick and/or rapid) or chronic (slow and/or prolonged) contraction, stretching, or torsion. In such applications, the hinge points between a floating rigid section and flexible adhered sections may be modified in order to align with and counteract or mitigate the predominant direction of the force acting on the patch. In some device situations or configurations, the strength and direction of the acute or chronic force may be so strong that the forces imparted on the device adhesive surfaces or components may be distributed differently in addition to or as an alternative to the hinge described above.

Further, the device construction can be made in such a way that the housing is fashioned so that the axes of the housing are structured and placed along or against the direction of various forces, possibly during certain states, such as sleeping, so that the device itself can help counteract these forces and improve long-term adhesion.

Advantageously, the patch described herein can provide long-term adhesion to the skin. Having the various flexible portions and/or hinged portions can compensate for stressed caused as the skin stretches or bends, while allowing the rigid portion to float about the skin. As a result, the devices described herein can adhere to the skin substantially continuously tor more than 24 hours, such as greater than 3 days, for example, greater than 7 days, greater than 14 days, or greater than 21 days.

Another mechanism for adhering a patch to the skin long-term is described with respect to FIGS. **7-10**. As shown in the embodiments of FIGS. **7-10**, one or more parts of the patch are used in a temporary fashion in order to improve adhesion. The adhesive used in the embodiments described below can include a hydrocolloid or a pressure-sensitive adhesive, such as polyacrylate, polyisobutylenes, or polysiloxane.

In one embodiment, shown in FIGS. **7**A and **7**B, the patch **700** can be surrounded with an adhesive **760** having multiple covers **701**, **703**, **705** thereon that can be peeled away in a sequence to expose strips of adhesive **760** underneath. The covers **701**, **703**, **705** can be concentric with one another and be configured to be pulled off separately and sequentially starting from the inside of the patch **700**. Each additional exposed area of adhesive **760** can increase the adhesion life of the patch **700**. Although only three covers are shown in FIG. **7**A, other numbers, such as 2, 4, 5, or more are possible. Further, each electrode **124**, **126** of the patch **700** can include a barrier **714**, **716** to protect the electrodes **124**, **126** from shortage.

In another embodiment, shown in FIGS. **8**A and **8**B, each electrode **124**, **126** can be surrounded by a patch of adhesive **864**, **866**. Accordingly, a set of covers **801**, **803**, **805**, **807** can be positioned sequentially around each of the electrodes **124**, **126** over the adhesive **864**, **866**. The covers **801**, **803**, **805**, **807** can be concentric with one another and be configured to be pulled off sequentially starting from the inside. Each additional exposed strip of adhesive **864**, **866** can increase the adhesion life of the patch **100**. Although only four covers are shown in FIG. **8**A, other numbers, such as 2, 3, 5, or more are possible. Further, each electrode **124**, **126** of the patch **800** can include a barrier **814**, **816** to protect from shortage.

Referring to FIGS. **9**A-**9**B, in other embodiments, shells or layers **901**, **902**, **903** can extend over all or a portion of the patch **900**. Each layer **901**, **902**, **903** can include a strip of adhesive **962** on the bottom surface and an adhesion guard **982** protecting the adhesive. As shown in FIG. **913**, as the patch **900** is worn over a period of time, the layers **901**, **902**, **903** can be sequentially removed. As a new layer is exposed, the adhesive guard **982** of that layer can be peeled away such that the adhesive **962** of the new layer can be used to adhere the patch **900** to the skin. In a similar embodiment, referring to FIGS. **10**A-**10**B, each of the layers **1001**, **1002**, **1003** can include multiple portions of adhesive to help adhere the layer to both the skin and the patch itself. As with the embodiments of FIGS. **7-8**, the number of layers in the embodiments of FIGS. **9** and **10** can vary. For example, there can be 2, 3, 4, or 5 or more layers.

In some embodiments, the layers or covers of the embodiments described herein can be added to the device over time to improve adhesion. Further, the multiple layers or covers of the embodiments described herein can be partially overlapped. Further, in some embodiments, the strips of adhesive can be overlapped.

Advantageously, the use of multiple covers or layers can assist in the adhesive performance of a base or core device because the added surface area or adhesive force of the combined outer layer aids in preventing layer pull away and/or may act to spread forces being experienced away from the core device by spreading those forces over a larger area.

Referring to FIGS. **11** and **12**, an open cell structured support **1330** or porous foam can be used to support a more rigid or less flexible portion **1302** of the patch **1300**, As shown in FIG. **11**, the open cell structured support **1330** can fully fill an area below the rigid portion **1302**. Alternatively, as shown in FIG. **12**, the open cell structured support **1330** can be an annular shape or have some other configuration that includes spaces between adjacent portions of the support. The open cell structured support **1302** may be attached to both the skin and to the rigid portion, to only the rigid portion, or to only the skin. Because of the open cell structure of the support, the flexible movement of the skin can be absorbed by the structure entirely or partially such that the rigid portion does not impact or has a reduced impact on the ability of the device to accommodate movement and remain affixed. In addition, the open cell support may have a thickness selected to enhance patient comfort so that the more rigid portion of a device does not push against the skin. In one aspect, the open cell structure is a biocompatible foam material. In another aspect, the open cell material is positioned between an electronics module on the device and the skin when worn by a patient. The open cell support can advantageously absorb fluids to keep the electrodes from shorting.

Referring to FIG. **13**, the patch can have a shell design. Adhesive can be placed on the perimeter edge of the bottom ring. The circuit board and electrode unit can be dropped into the bottom ring, and a shell can be dropped on top of the circuit board and electrode. The perimeter adhesive can create a watertight chamber therein.

The shape of a particular electronic device embodiment may vary. The shape, footprint, perimeter or boundary of the device may be a circle or circular (see FIG. **13**A), an oval (see FIG. **1**A, **2**A), a triangle or generally triangular (see FIG. **1**F) or a compound curve. Examples of a device embodiments having a compound curve shape are shown in FIGS. **2**B, **2**B, **3**, **6**A, **7**A, and **8**A. In some embodiments, the compound curve includes one or more concave curves and one or more convex curves. FIG. **3** illustrates a device having a convex surface along the top (where reference **102**

indicates), a concave surface along the bottom and convex shaped edges around the electrodes **124**, **126**. FIGS. **2**B and **2**C illustrate a device embodiment having a convex shape on either side of the electronics **108** and around the electrodes **124**, **126**. The convex shapes are separated by a concave portion. The concave portion is between the convex portion on the electronics and the convex portion on the electrodes. In some embodiments, the concave portion corresponds at least partially with a hinge, hinge region or area of reduced.

While described in the context of a heart monitor, the device adhesion improvements described herein are not so limited. The improvement described in this application may be applied to any of a wide variety of conventional physiological data monitoring, recording and/or transmitting devices. The improved adhesion design features may also be applied to conventional devices useful in the electronically controlled and/or time released delivery of pharmacological agents or blood testing, such as glucose monitors or other blood testing devices. As such, the description, characteristics and functionality of the components described herein may be modified as needed to include the specific components of a particular application such as electronics, antenna, power supplies or charging connections, data ports or connections for down loading or off loading information from the device, adding or offloading fluids from the device, monitoring or sensing elements such as electrodes, probes or sensors or any other component or components needed in the device specific function. In addition or alternatively, devices described herein may be used to detect, record, or transmit signals or information related to signals generated by a body including but not limited to one or more of EKG, EEG, and/or EMG.

What is claimed is:

1. An electronic device for long-term adhesion to a user, the device comprising:

a housing comprising a physiologic data collection circuit;

an electrode-supporting section comprising a first substrate layer, a second substrate layer, and a lower adhesive layer positioned on a bottom surface, the lower adhesive layer providing adhesion to the skin of the user;

an electrode positioned on the bottom surface of the electrode-supporting section, the electrode electrically connected to the physiologic data collection circuit; and

wherein the first substrate layer is positioned over the electrode and extends horizontally away from the housing beyond a boundary of the electrode; and

wherein the second substrate layer is positioned over the first substrate layer and extends horizontally beyond a boundary of the first substrate layer.

2. The electronic device of claim **1**, wherein the electrode supporting section further comprises a third substrate layer adhered to the first substrate layer.

3. The electronic device of claim **1**, further comprising an upper adhesive layer positioned on the underside of the first substrate layer.

4. The electronic device of claim **1**, wherein the lower adhesive layer extends at least partially below the housing.

5. The electronic device of claim **1**, further comprising a flap extending beneath the housing.

6. The electronic device of claim **1**, wherein the housing is rigid.

7. The electronic device of claim **1**, wherein the housing is configured to remain connected to the electrode-supporting section when the housing is tilted at an angle relative the lower adhesive layer in response to movement of the user.

8. The electronic device of claim **1**, further comprising a hinge portion adjacent the housing.

9. The electronic device of claim **1**, wherein the lower adhesive layer comprises a hydrocolloid adhesive.

10. The electronic device of claim **1**, wherein the physiologic data collection circuit is configured to collect cardiac rhythm data from the user.

* * * * *

EXHIBIT B

US012161473B1

(12) **United States Patent**
Felix et al.

(10) **Patent No.: US 12,161,473 B1**
(45) **Date of Patent: Dec. 10, 2024**

(54) **ELECTROCARDIOGRAPHY PATCH**

(71) Applicant: **Bardy Diagnostics, Inc.**, Bellevue, WA (US)

(72) Inventors: **Jason Felix**, Vashon Island, WA (US); **Jon Mikalson Bishay**, Seattle, WA (US); **Gust H. Bardy**, Carnation, WA (US)

(73) Assignee: **BARDY DIAGNOSTICS, INC.**, Vashon, WA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **18/800,675**

(22) Filed: **Aug. 12, 2024**

Related U.S. Application Data

(63) Continuation of application No. 18/647,762, filed on Apr. 26, 2024, now Pat. No. 12,089,943, which is a (Continued)

(51) **Int. Cl.**
A61B 5/335 (2021.01)
A61B 5/00 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 5/335*** (2021.01); ***A61B 5/0006*** (2013.01); ***A61B 5/0022*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC G16H 40/63; G16H 40/67; A61B 2560/0214; A61B 2560/0443; A61B 5/0006; A61B 5/0022; A61B 5/02055; A61B 5/021; A61B 5/03; A61B 5/0816; A61B 5/087; A61B 5/1118; A61B 5/14532; A61B 5/14542; A61B 5/14551; A61B 5/259; A61B 5/282; A61B 5/335;
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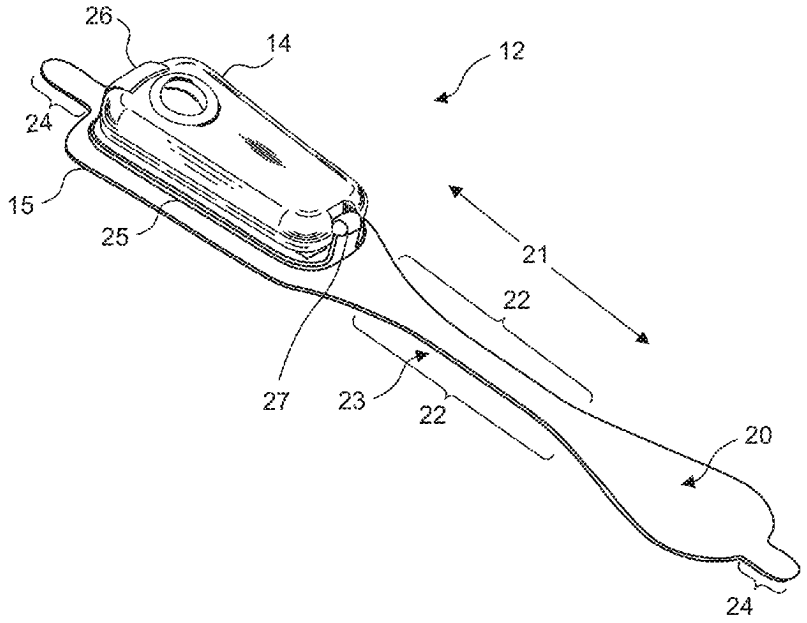
Primary Examiner — George Manuel
(74) *Attorney, Agent, or Firm* — K&L Gates LLP

(57) **ABSTRACT**

An apparatus is provided. A strip has first and second end sections, and a first face and second face. Two electrocardiographic electrodes are provided on the strip with one of the electrocardiographic electrodes provided on the first face of the first end section of the strip and another of the electrocardiographic electrodes positioned on the first face on the second end section of the strip. A flexible circuit is mounted to the second face of the strip and includes a circuit trace electrically coupled to each of the electrocardiographic electrodes. The apparatus includes a wireless transceiver and a battery.

30 Claims, 8 Drawing Sheets



Related U.S. Application Data

continuation of application No. 18/353,398, filed on Jul. 17, 2023, which is a continuation of application No. 17/946,933, filed on Sep. 16, 2022, now Pat. No. 11,723,575, which is a continuation of application No. 17/367,476, filed on Jul. 5, 2021, now Pat. No. 11,445,967, which is a continuation of application No. 17/119,945, filed on Dec. 11, 2020, now Pat. No. 11,051,743, which is a continuation of application No. 16/241,929, filed on Jan. 7, 2019, now Pat. No. 10,888,239, which is a continuation of application No. 15/818,437, filed on Nov. 20, 2017, now Pat. No. 10,172,534, which is a continuation of application No. 15/256,266, filed on Sep. 2, 2016, now Pat. No. 9,820,665, which is a continuation of application No. 14/082,071, filed on Nov. 15, 2013, now Pat. No. 9,433,367, which is a continuation-in-part of application No. 14/080,717, filed on Nov. 14, 2013, now Pat. No. 9,545,204, and a continuation-in-part of application No. 14/080,725, filed on Nov. 14, 2013, now Pat. No. 9,730,593.

(60) Provisional application No. 61/882,403, filed on Sep. 25, 2013.

(51) **Int. Cl.**

A61B 5/0205	(2006.01)
A61B 5/145	(2006.01)
A61B 5/259	(2021.01)
A61B 5/282	(2021.01)
G16H 40/67	(2018.01)
A61B 5/021	(2006.01)
A61B 5/03	(2006.01)
A61B 5/08	(2006.01)
A61B 5/087	(2006.01)
A61B 5/11	(2006.01)
A61B 5/1455	(2006.01)
A61B 5/349	(2021.01)

(52) **U.S. Cl.**

CPC ***A61B 5/02055*** (2013.01); ***A61B 5/14532*** (2013.01); ***A61B 5/14542*** (2013.01); ***A61B 5/259*** (2021.01); ***A61B 5/282*** (2021.01); ***A61B 5/6823*** (2013.01); ***A61B 5/6833*** (2013.01); ***A61B 5/7405*** (2013.01); ***A61B 5/7455*** (2013.01); ***A61B 5/7475*** (2013.01); ***G16H 40/67*** (2018.01); *A61B 5/021* (2013.01); *A61B 5/03* (2013.01); *A61B 5/0816* (2013.01); *A61B 5/087* (2013.01); *A61B 5/1118* (2013.01); *A61B 5/14551* (2013.01); *A61B 5/349* (2021.01); *A61B 2560/0214* (2013.01); *A61B 2560/0443* (2013.01)

(58) **Field of Classification Search**

CPC A61B 5/349; A61B 5/6823; A61B 5/6833; A61B 5/7405; A61B 5/7455; A61B 5/7475

See application file for complete search history.

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Fig. 1.

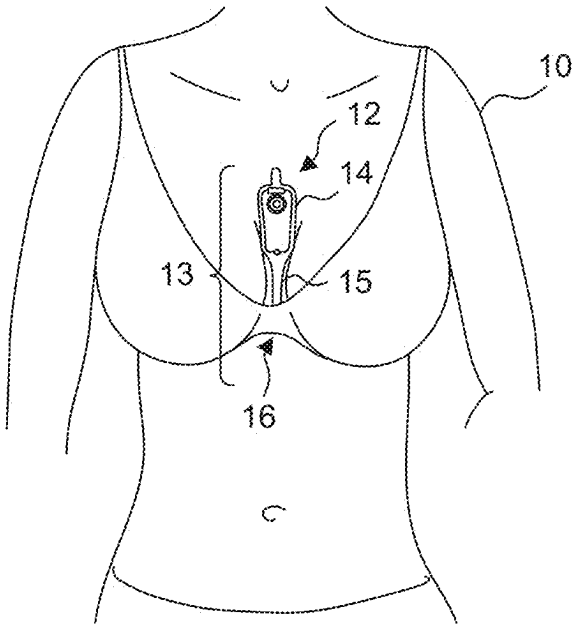

Fig. 2.

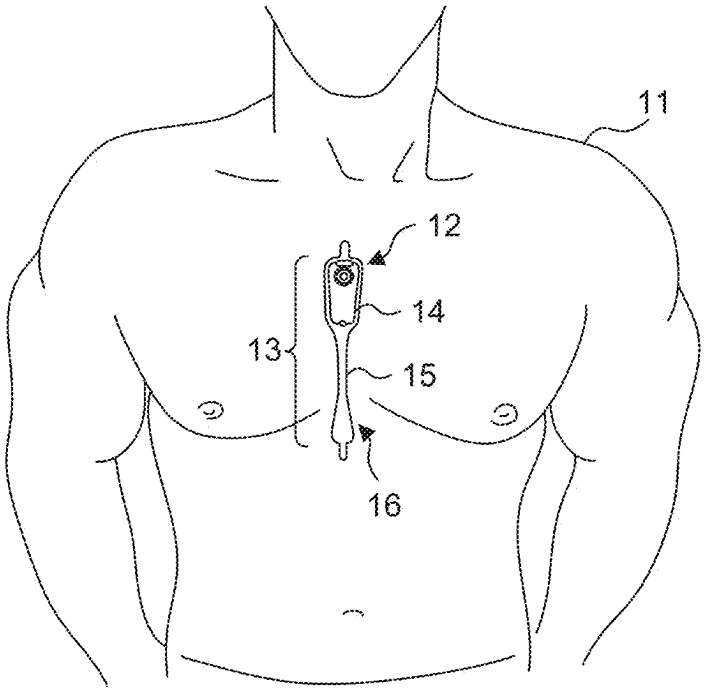

Fig. 3.

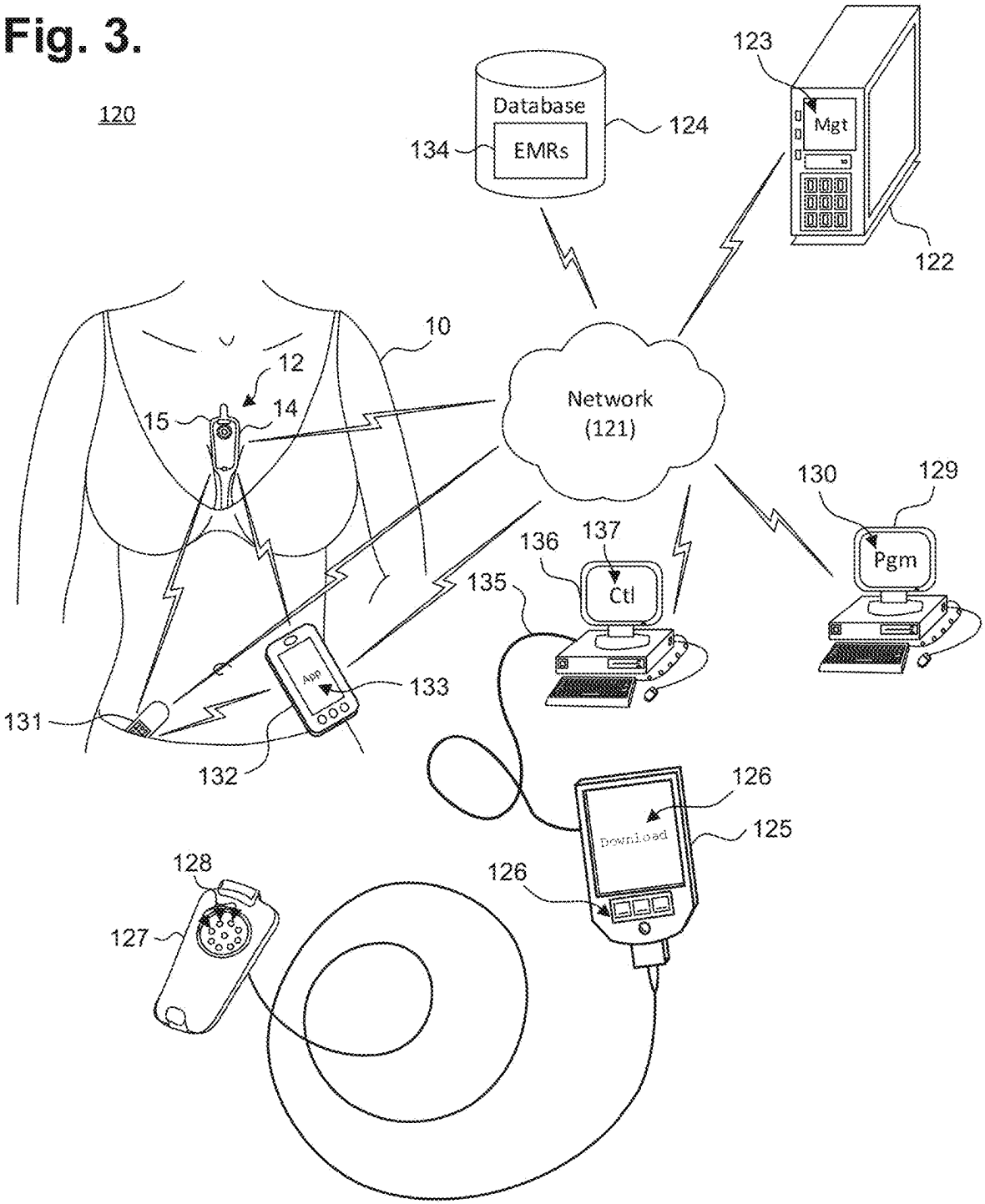
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Fig. 4.

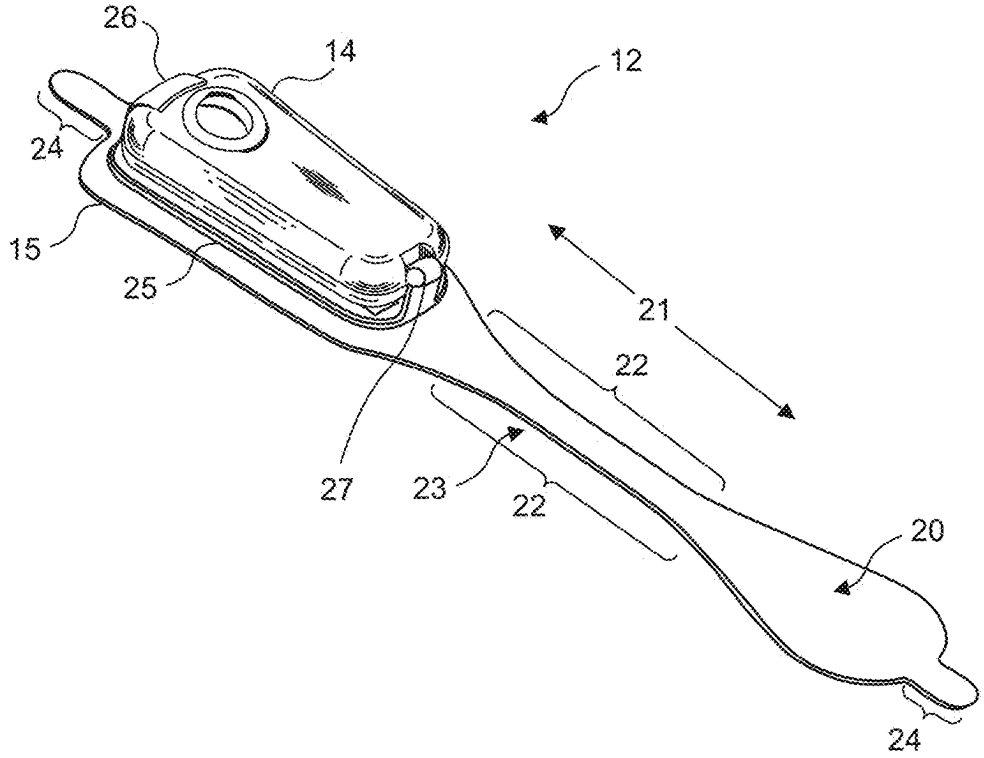


Fig. 5.

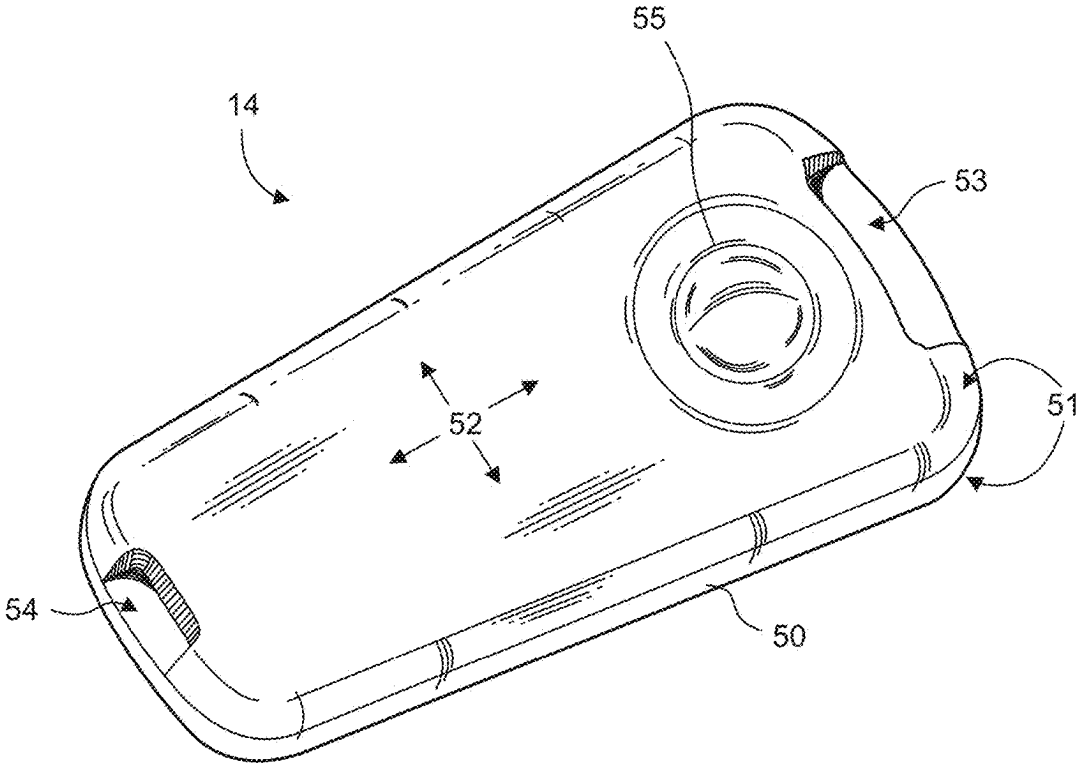


Fig. 6.

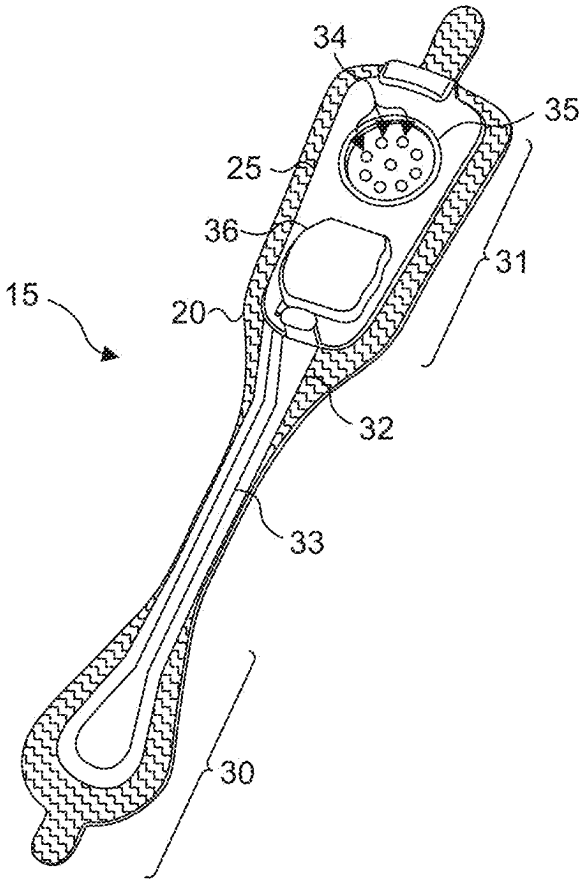


Fig. 7.

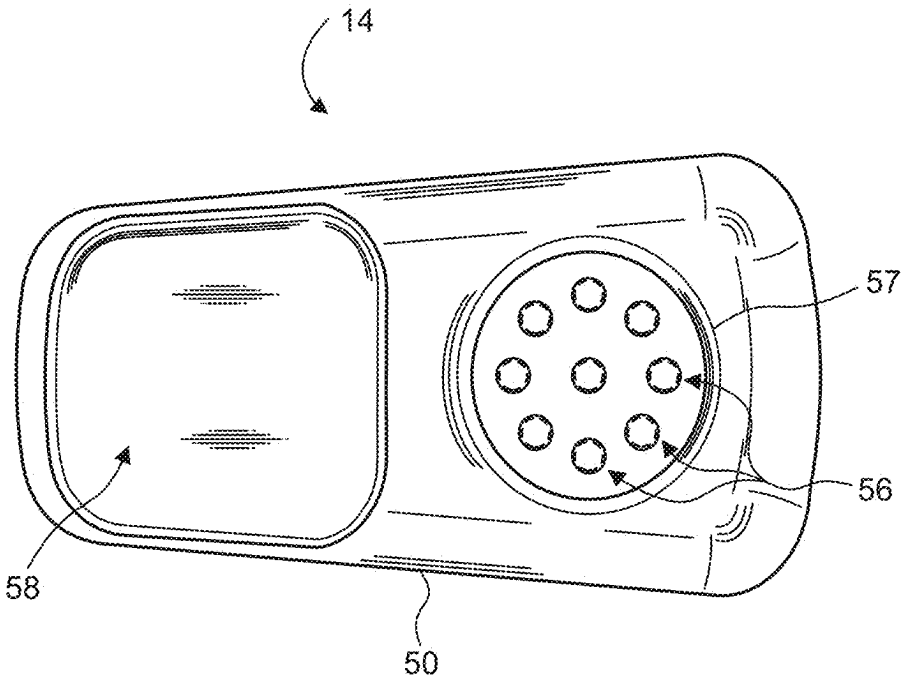


Fig. 8.

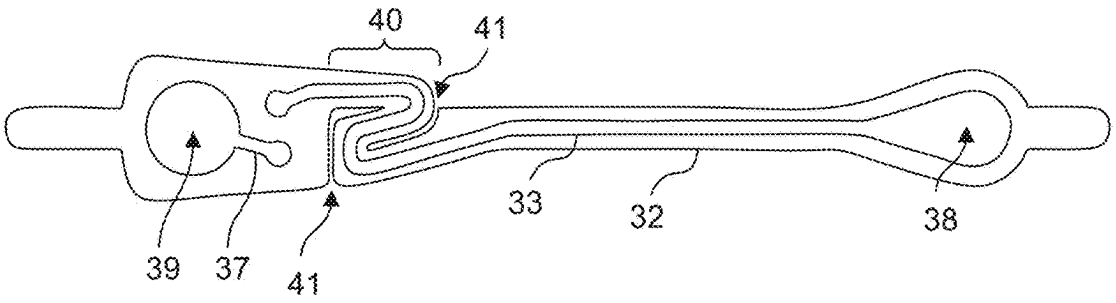


Fig. 9.

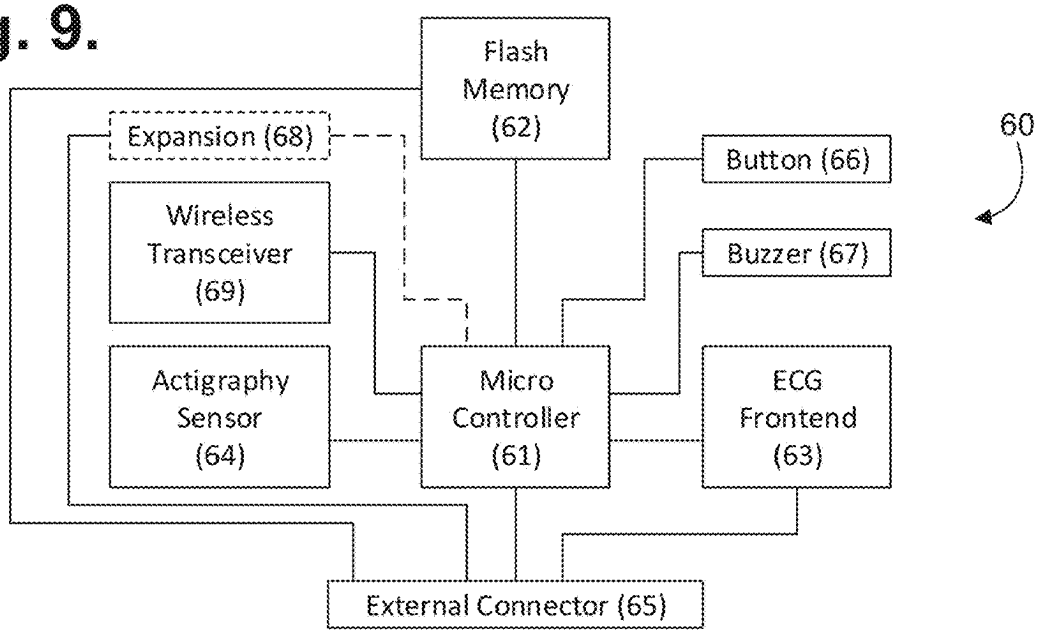


Fig. 10.

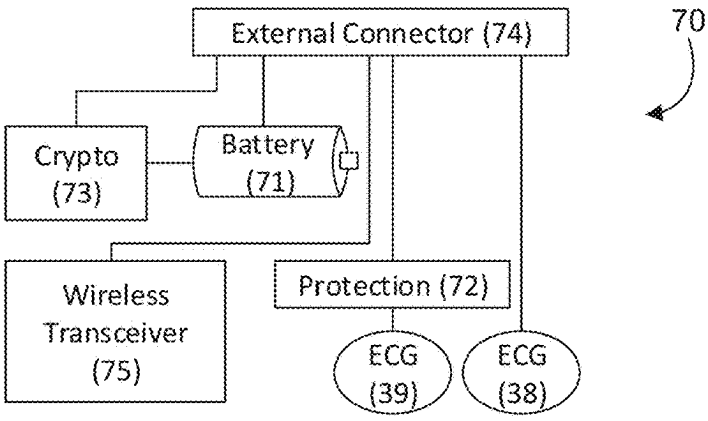
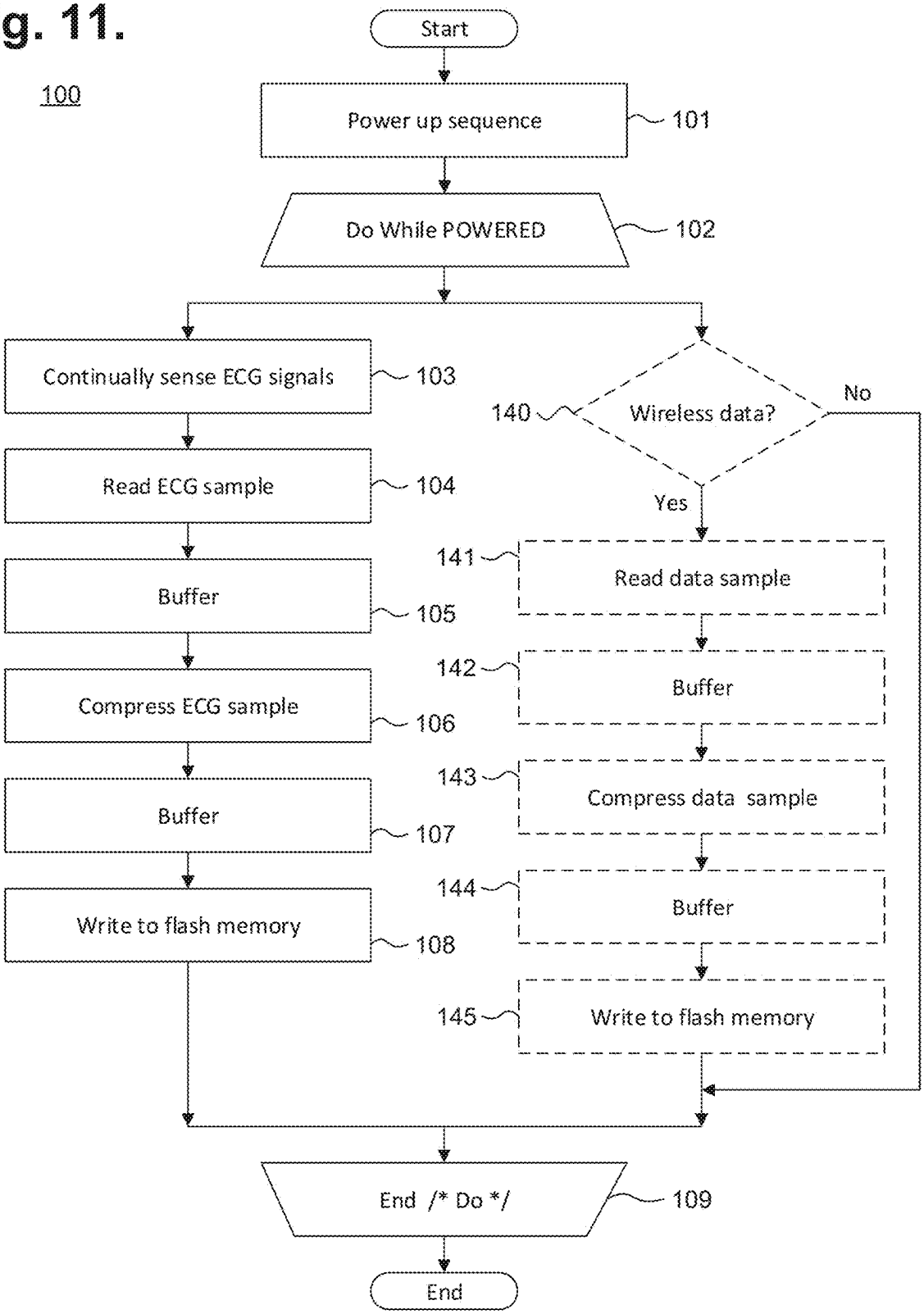


Fig. 11.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Start
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101
Do While POWERED
102
Continually sense ECG signals
103
Read ECG sample
104
Buffer
105
Compress ECG sample
106
Buffer
107
Write to flash memory
108
140
Wireless data?
No
Yes
141
Read data sample
142
Buffer
143
Compress data sample
144
Buffer
145
Write to flash memory
End /* Do */
109
End

Fig. 12.

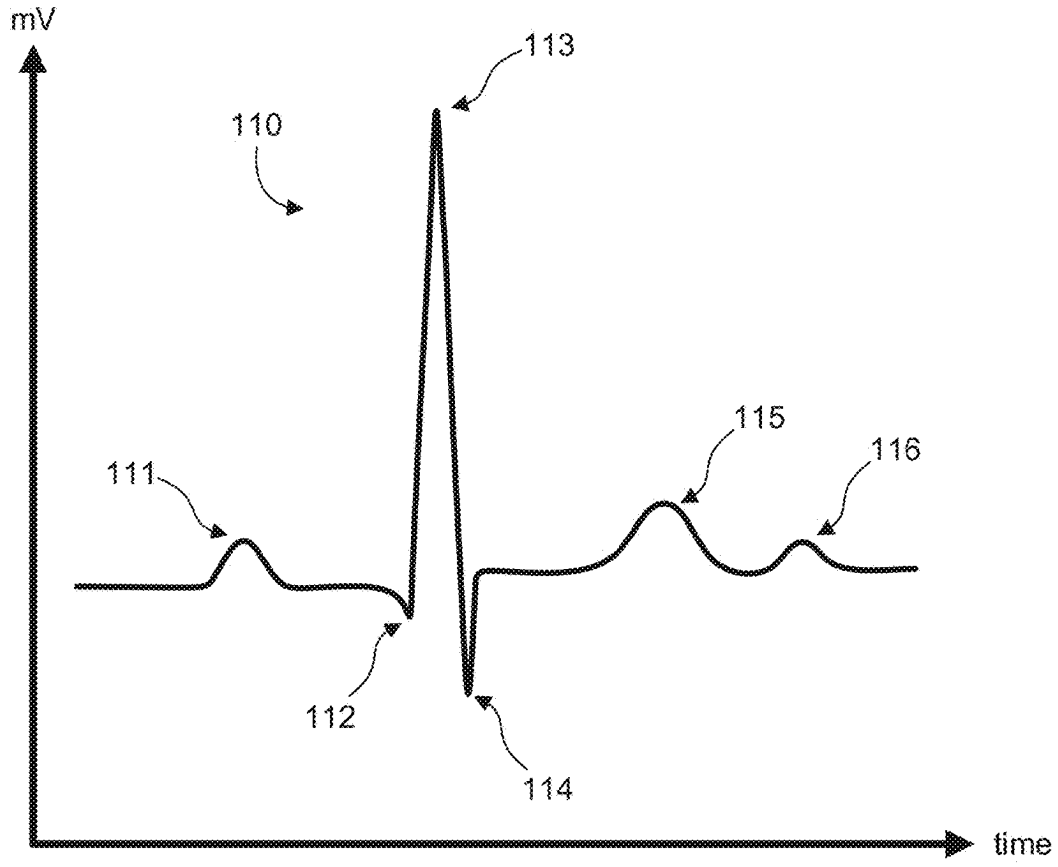
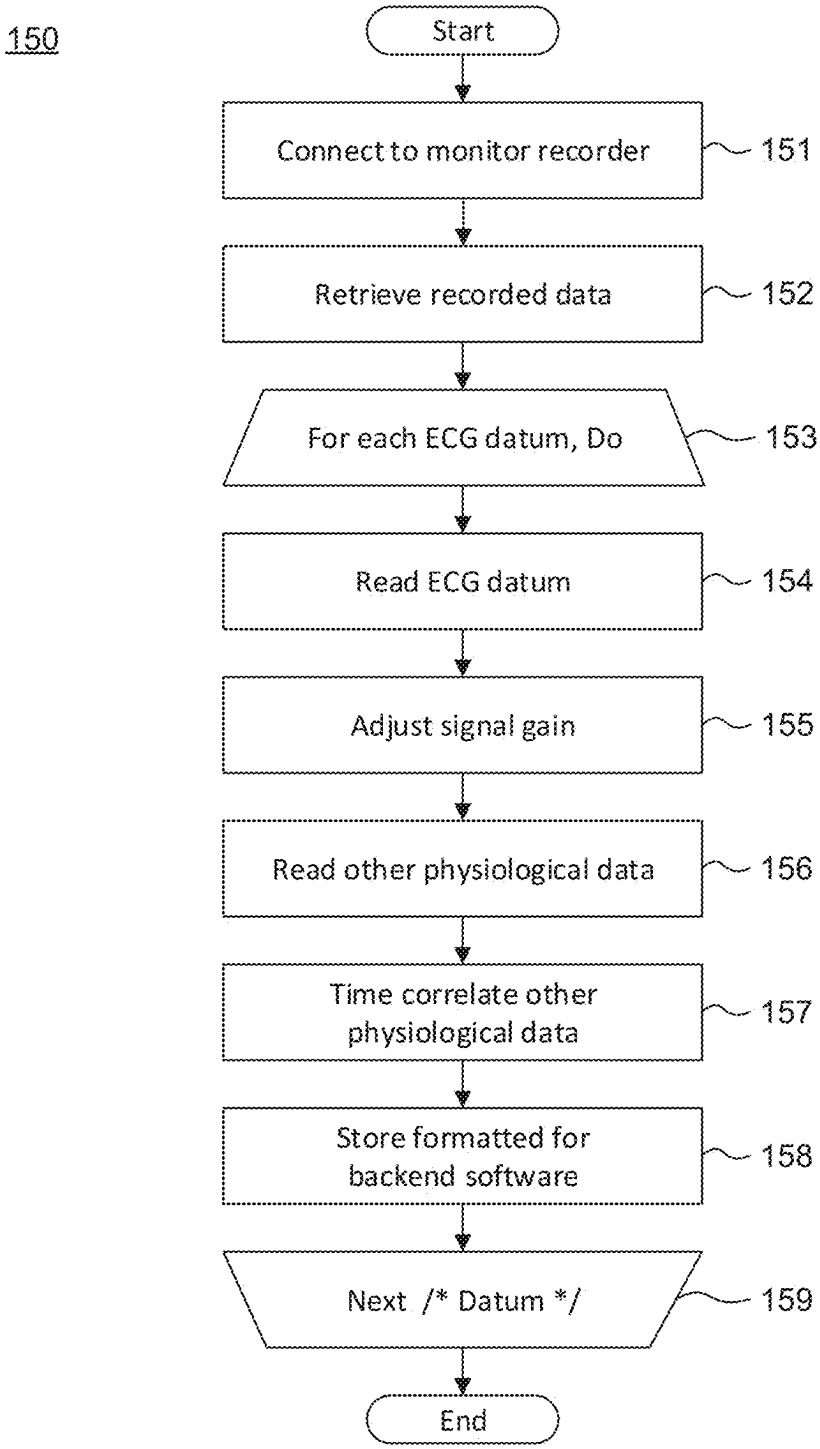


Fig. 13.


150
Start
Connect to monitor recorder
151
Retrieve recorded data
152
For each ECG datum, Do
153
Read ECG datum
154
Adjust signal gain
155
Read other physiological data
156
Time correlate other physiological data
157
Store formatted for backend software
158
Next /* Datum */
159
End

ELECTROCARDIOGRAPHY PATCH

PRIORITY CLAIM AND CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 18/647,762, filed Apr. 26, 2024, titled ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 18/353,398, filed Jul. 17, 2023, titled ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 17/946,933, filed Sep. 16, 2022, titled ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 17/367,476, filed Jul. 5, 2021, titled ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 17/119,945, filed Dec. 11, 2020, titled ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 16/241,929, filed Jan. 7, 2019, titled REMOTE INTERFACING ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 15/818,437, filed Nov. 20, 2017, titled REMOTE INTERFACING ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 15/256,266, filed Sep. 2, 2016, titled REMOTE INTERFACING OF EXTENDED WEAR ELECTROCARDIOGRAPHY AND PHYSIOLOGICAL SENSOR MONITOR, which is a continuation of U.S. patent application Ser. No. 14/082,071, filed Nov. 15, 2013, titled REMOTE INTERFACING OF EXTENDED WEAR ELECTROCARDIOGRAPHY AND PHYSIOLOGICAL SENSOR MONITOR, which is a continuation-in-part of U.S. patent application Ser. No. 14/080,717, filed Nov. 14, 2013, titled EXTENDED WEAR ELECTROCARDIOGRAPHY PATCH, which claims priority to U.S. Provisional Patent App. No. 61/882,403, filed Sep. 25, 2013, titled LONG-TERM WEARABLE PHYSIOLOGICAL MONITOR. U.S. patent application Ser. No. 14/082,071 is also a continuation-in-part of U.S. patent application Ser. No. 14/080,725, filed Nov. 14, 2013, titled EXTENDED WEAR AMBULATORY ELECTROCARDIOGRAPHY AND PHYSIOLOGICAL SENSOR MONITOR, which claims priority to U.S. Provisional Patent App. No. 61/882,403, filed Sep. 25, 2013, titled LONG-TERM WEARABLE PHYSIOLOGICAL MONITOR. The entire contents of these applications are incorporated by reference herein in their entirely and relied upon.

FIELD

This application relates in general to electrocardiographic monitoring and, in particular, to an electrocardiography patch.

BACKGROUND

The heart emits electrical signals as a by-product of the propagation of the action potentials that trigger depolarization of heart fibers. An electrocardiogram (ECG) measures and records such electrical potentials to visually depict the electrical activity of the heart over time. Conventionally, a standardized set format 12-lead configuration is used by an ECG machine to record cardiac electrical signals from well-established traditional chest locations. Electrodes at the end of each lead are placed on the skin over the anterior thoracic region of the patient's body to the lower right and to the lower left of the sternum, on the left anterior chest, and on the limbs. Sensed cardiac electrical activity is represented by PQRSTU waveforms that can be interpreted post-ECG recordation to derive heart rate and physiology. The P-wave represents atrial electrical activity. The QRSTU components represent ventricular electrical activity.

An ECG is a tool used by physicians to diagnose heart problems and other potential health concerns. An ECG is a snapshot of heart function, typically recorded over 12 seconds, that can help diagnose rate and regularity of heartbeats, effect of drugs or cardiac devices, including pacemakers and implantable cardioverter-defibrillators (ICDs), and whether a patient has heart disease. ECGs are used in-clinic during appointments, and, as a result, are limited to recording only those heart-related aspects present at the time of recording. Sporadic conditions that may not show up during a spot ECG recording require other means to diagnose them. These disorders include fainting or syncope; rhythm disorders, such as tachyarrhythmias and bradyarrhythmias; apneic episodes; and other cardiac and related disorders. Thus, an ECG only provides a partial picture and can be insufficient for complete patient diagnosis of many cardiac disorders.

Diagnostic efficacy can be improved, when appropriate, through the use of long-term extended ECG monitoring. Recording sufficient ECG and related physiology over an extended period is challenging, and often essential to enabling a physician to identify events of potential concern. A 30-day observation period is considered the "gold standard" of ECG monitoring, yet achieving a 30-day observation day period has proven unworkable because such ECG monitoring systems are arduous to employ, cumbersome to the patient, and excessively costly. Ambulatory monitoring in-clinic is implausible and impracticable. Nevertheless, if a patient's ECG could be recorded in an ambulatory setting, thereby allowing the patient to engage in activities of daily living, the chances of acquiring meaningful information and capturing an abnormal event while the patient is engaged in normal activities becomes more likely to be achieved.

For instance, the long-term wear of ECG electrodes is complicated by skin irritation and the inability ECG electrodes to maintain continual skin contact after a day or two. Moreover, time, dirt, moisture, and other environmental contaminants, as well as perspiration, skin oil, and dead skin cells from the patient's body, can get between an ECG electrode, the non-conductive adhesive used to adhere the ECG electrode, and the skin's surface. All of these factors adversely affect electrode adhesion and the quality of cardiac signal recordings. Furthermore, the physical movements of the patient and their clothing impart various compressional, tensile, and torsional forces on the contact point of an ECG electrode, especially over long recording times, and an inflexibly fastened ECG electrode will be prone to becoming dislodged. Moreover, dislodgment may occur unbeknownst to the patient, making the ECG recordings worthless. Further, some patients may have skin that is susceptible to itching or irritation, and the wearing of ECG electrodes can aggravate such skin conditions. Thus, a patient may want or need to periodically remove or replace ECG electrodes during a long-term ECG monitoring period, whether to replace a dislodged electrode, reestablish better adhesion, alleviate itching or irritation, allow for cleansing of the skin, allow for showering and exercise, or for other purpose. Such replacement or slight alteration in electrode location actually facilitates the goal of recording the ECG signal for long periods of time.

Conventionally, Holter monitors are widely used for long-term extended ECG monitoring. Typically, they are used for only 24-48 hours. A typical Holter monitor is a wearable and

portable version of an ECG that include cables for each electrode placed on the skin and a separate battery-powered ECG recorder. The cable and electrode combination (or leads) are placed in the anterior thoracic region in a manner similar to what is done with an in-clinic standard ECG machine. The duration of a Holter monitoring recording depends on the sensing and storage capabilities of the monitor, as well as battery life. A "looping" Holter monitor (or event) can operate for a longer period of time by overwriting older ECG tracings, thence "recycling" storage in favor of extended operation, yet at the risk of losing event data. Although capable of extended ECG monitoring, Holter monitors are cumbersome, expensive and typically only available by medical prescription, which limits their usability. Further, the skill required to properly place the electrodes on the patient's chest hinders or precludes a patient from replacing or removing the precordial leads and usually involves moving the patient from the physician office to a specialized center within the hospital or clinic.

The ZIO XT Patch and ZIO Event Card devices, manufactured by iRhythm Tech., Inc., San Francisco, CA, are wearable stick-on monitoring devices that are typically worn on the upper left pectoral region to respectively provide continuous and looping ECG recording. The location is used to simulate surgically implanted monitors. Both of these devices are prescription-only and for single patient use. The ZIO XT Patch device is limited to a 14-day monitoring period, while the electrodes only of the ZIO Event Card device can be worn for up to 30 days. The ZIO XT Patch device combines both electronic recordation components, including battery, and physical electrodes into a unitary assembly that adheres to the patient's skin. The ZIO XT Patch device uses adhesive sufficiently strong to support the weight of both the monitor and the electrodes over an extended period of time and to resist disadherance from the patient's body, albeit at the cost of disallowing removal or relocation during the monitoring period. Moreover, throughout monitoring, the battery is continually depleted and battery capacity can potentially limit overall monitoring duration. The ZIO Event Card device is a form of downsized Holter monitor with a recorder component that must be removed temporarily during baths or other activities that could damage the non-waterproof electronics. Both devices represent compromises between length of wear and quality of ECG monitoring, especially with respect to ease of long term use, female-friendly fit, and quality of atrial (P-wave) signals.

In addition, with the advent of wireless communications and wearable computing, other types of personal ambulatory monitors, of varying degrees of sophistication, have become increasingly available. For example, adherents to the so-called "Quantified Self" movement combine wearable sensors and wearable computing to self-track activities of their daily lives, including inputs, states, and performance. The Nike+FuelBand, manufactured by Nike Inc., Beaverton, OR, for instance, provides an activity tracker that is worn on the wrist and allows the wearer to temporally track the number of foot steps taken each day and an estimation of the calories burned. The activity tracker can interface with a smart phone device to allow a wearer to monitor their progress towards a fitness goal. Such quantified physiology, however, is typically tracked for only the personal use of the wearer and is not time-correlated to physician-supervised monitoring.

Therefore, a need remains for an extended wear continuously recording ECG monitor practicably capable of being worn for a long period of time in both men and women and capable of recording atrial signals reliably.

A further need remains for facilities to integrate wider-ranging physiological and "life tracking"-type data into long-term ECG and physiological data monitoring.

SUMMARY

Physiological monitoring can be provided through a wearable monitor that includes two components, a flexible extended wear electrode patch and a removable reusable monitor recorder. The wearable monitor sits centrally (in the midline) on the patient's chest along the sternum oriented top-to-bottom. The placement of the wearable monitor in a location at the sternal midline (or immediately to either side of the sternum), with its unique narrow "hourglass"-like shape, benefits long-term extended wear by removing the requirement that ECG electrodes be continually placed in the same spots on the skin throughout the monitoring period. Instead, the patient is free to place an electrode patch anywhere within the general region of the sternum, the area most likely to record high quality atrial signals or P-waves. The wearable monitor can also interoperate wirelessly with other wearable physiology and activity sensors and with wearable or mobile communications devices, including so-called "smart phones," to download monitoring data either in real-time or in batches. The monitor recorder can also be equipped with a wireless transceiver to either provide data or other information to, or receive data or other information from, an interfacing wearable physiology and activity sensor, or wearable or mobile communications devices for relay to a further device, such as a server, analysis, or other purpose.

One embodiment provides a remotely-interfaceable electrocardiography patch. The remotely-interfaceable electrocardiography patch includes a backing formed of a strip of material and an electrocardiographic electrode on each end of the backing to capture electrocardiographic signals. A flexible circuit includes a pair of circuit traces electrically coupled to the electrocardiographic electrodes. A wireless transceiver communicates at least one of the electrocardiographic signals and other physiological measures with one or more of a physiology and activity sensor, communication device, server, and personal computer.

A further embodiment provides an electrocardiography patch. The patch includes a backing and at least two electrocardiographic electrodes each positioned on the backing, across from another of the electrocardiographic electrodes, to capture electrocardiographic signals. A flexible circuit includes a pair of circuit traces electrically coupled to the electrocardiographic electrodes. A wireless transceiver communicates at least a portion of the electrocardiographic signals.

A still further embodiment provides an apparatus. A strip has first and second end sections, and a first surface and second surface. Two electrocardiographic electrodes are provided on the strip with one of the electrocardiographic electrodes provided on the first surface of the first end section of the strip and another of the electrocardiographic electrodes positioned on the first surface on the second end section of the strip. A flexible circuit is mounted to the second surface of the strip and includes a circuit trace electrically coupled to each of the electrocardiographic electrodes. A wireless transceiver is affixed on one of the first or second end sections, and a battery is positioned on one of

the first or second end sections. A processor is positioned on one of the first or second end sections and is housed separate from the battery.

The monitoring patch is especially suited to the female anatomy. The narrow longitudinal midsection can fit nicely within the intermammary cleft of the breasts without inducing discomfort, whereas conventional patch electrodes are wide and, if adhesed between the breasts, would cause chafing, irritation, frustration, and annoyance, leading to low patient compliance.

The foregoing aspects enhance ECG monitoring performance and quality, facilitating long-term ECG recording, critical to accurate arrhythmia diagnosis.

In addition, the foregoing aspects enhance comfort in women (and certain men), but not irritation of the breasts, by placing the monitoring patch in the best location possible for optimizing the recording of cardiac signals from the atrium, another feature critical to proper arrhythmia diagnosis.

Finally, the foregoing aspects as relevant to monitoring are equally applicable to recording other physiological measures, such as temperature, respiratory rate, blood sugar, oxygen saturation, and blood pressure, as well as other measures of body chemistry and physiology.

Still other embodiments will become readily apparent to those skilled in the art from the following detailed description, wherein are described embodiments by way of illustrating the best mode contemplated. As will be realized, other and different embodiments are possible and the embodiments' several details are capable of modifications in various obvious respects, all without departing from their spirit and the scope. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not as restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1** and **2** are diagrams showing, by way of examples, an extended wear electrocardiography and physiological sensor monitor respectively fitted to the sternal region of a female patient and a male patient.

FIG. **3** is a functional block diagram showing a system for remote interfacing of an extended wear electrocardiography and physiological sensor monitor in accordance with one embodiment.

FIG. **4** is a perspective view showing an extended wear electrode patch with a monitor recorder inserted.

FIG. **5** is a perspective view showing the monitor recorder of FIG. **4**.

FIG. **6** is a perspective view showing the extended wear electrode patch of FIG. **4** without a monitor recorder inserted.

FIG. **7** is a bottom plan view of the monitor recorder of FIG. **4**.

FIG. **8** is a top view showing the flexible circuit of the extended wear electrode patch of FIG. **4** when mounted above the flexible backing.

FIG. **9** is a functional block diagram showing the component architecture of the circuitry of the monitor recorder of FIG. **4**.

FIG. **10** is a functional block diagram showing the circuitry of the extended wear electrode patch of FIG. **4**.

FIG. **11** is a flow diagram showing a monitor recorder-implemented method for monitoring ECG data for use in the monitor recorder of FIG. **4**.

FIG. **12** is a graph showing, by way of example, a typical ECG waveform.

FIG. **13** is a flow diagram showing a method for offloading and converting ECG and other physiological data from an extended wear electrocardiography and physiological sensor monitor in accordance with one embodiment.

DETAILED DESCRIPTION

Physiological monitoring can be provided through a wearable monitor that includes two components, a flexible extended wear electrode patch and a removable reusable monitor recorder. FIGS. **1** and **2** are diagrams showing, by way of examples, an extended wear electrocardiography and physiological sensor monitor **12**, including a monitor recorder **14** in accordance with one embodiment, respectively fitted to the sternal region of a female patient **10** and a male patient **11**. The wearable monitor **12** sits centrally (in the midline) on the patient's chest along the sternum **13** oriented top-to-bottom with the monitor recorder **14** preferably situated towards the patient's head. In a further embodiment, the orientation of the wearable monitor **12** can be corrected post-monitoring, as further described infra. The electrode patch **15** is shaped to fit comfortably and conformal to the contours of the patient's chest approximately centered on the sternal midline **16** (or immediately to either side of the sternum **13**). The distal end of the electrode patch **15** extends towards the Xiphoid process and, depending upon the patient's build, may straddle the region over the Xiphoid process. The proximal end of the electrode patch **15**, located under the monitor recorder **14**, is below the manubrium and, depending upon patient's build, may straddle the region over the manubrium.

The placement of the wearable monitor **12** in a location at the sternal midline **16** (or immediately to either side of the sternum **13**) significantly improves the ability of the wearable monitor **12** to cutaneously sense cardiac electric signals, particularly the P-wave (or atrial activity) and, to a lesser extent, the QRS interval signals in the ECG waveforms that indicate ventricular activity, while simultaneously facilitating comfortable long-term wear for many weeks. The sternum **13** overlies the right atrium of the heart and the placement of the wearable monitor **12** in the region of the sternal midline **13** puts the ECG electrodes of the electrode patch **15** in a location better adapted to sensing and recording P-wave signals than other placement locations, say, the upper left pectoral region or lateral thoracic region or the limb leads. In addition, placing the lower or inferior pole (ECG electrode) of the electrode patch **15** over (or near) the Xiphoid process facilitates sensing of ventricular activity and provides superior recordation of the QRS interval.

When operated standalone, the monitor recorder **14** of the extended wear electrocardiography and physiological sensor monitor **12** senses and records the patient's ECG data into an onboard memory. In addition, the wearable monitor **12** can interoperate with other devices. FIG. **3** is a functional block diagram showing a system **120** for remote interfacing of an extended wear electrocardiography and physiological sensor monitor **12** in accordance with one embodiment. The monitor recorder **14** is a reusable component that can be fitted during patient monitoring into a non-conductive receptacle provided on the electrode patch **15**, as further described infra with reference to FIG. **4**, and later removed for offloading of stored ECG data or to receive revised programming. The monitor recorder **14** can then be connected to a download station **125**, which could be a programmer or other device that permits the retrieval of stored ECG monitoring data, execution of diagnostics on or programming of the monitor recorder **14**, or performance of other functions. The monitor

recorder **14** has a set of electrical contacts (not shown) that enable the monitor recorder **14** to physically interface to a set of terminals **128** on a paired receptacle **127** of the download station **125**. In turn, the download station **125** executes a communications or offload program **126** ("Offload") or similar program that interacts with the monitor recorder **14** via the physical interface to retrieve the stored ECG monitoring data. The download station **125** could be a server, personal computer, tablet or handheld computer, smart mobile device, or purpose-built programmer designed specific to the task of interfacing with a monitor recorder **14**. Still other forms of download station **125** are possible.

Upon retrieving stored ECG monitoring data from a monitor recorder **14**, middleware first operates on the retrieved data to adjust the ECG capture quality, as necessary, and to convert the retrieved data into a format suitable for use by third party post-monitoring analysis software, as further described infra with reference to FIG. **13**. The formatted data can then be retrieved from the download station **125** over a hard link **135** using a control program **137** ("Ctl") or analogous application executing on a personal computer **136** or other connectable computing device, via a communications link (not shown), whether wired or wireless, or by physical transfer of storage media (not shown). The personal computer **136** or other connectable device may also execute middleware that converts ECG data and other information into a format suitable for use by a third-party post-monitoring analysis program, as further described infra with reference to FIG. **13**. Note that formatted data stored on the personal computer **136** would have to be maintained and safeguarded in the same manner as electronic medical records (EMRs) **134** in the secure database **124**, as further discussed infra. In a further embodiment, the download station **125** is able to directly interface with other devices over a computer communications network **121**, which could be some combination of a local area network and a wide area network, including the Internet, over a wired or wireless connection.

A client-server model could be used to employ a server **122** to remotely interface with the download station **125** over the network **121** and retrieve the formatted data or other information. The server **122** executes a patient management program **123** ("Mgt") or similar application that stores the retrieved formatted data and other information in a secure database **124** cataloged in that patient's EMRs **134**. In addition, the patient management program **123** could manage a subscription service that authorizes a monitor recorder **14** to operate for a set period of time or under pre-defined operational parameters.

The patient management program **123**, or other trusted application, also maintains and safeguards the secure database **124** to limit access to patient EMRs **134** to only authorized parties for appropriate medical or other uses, such as mandated by state or federal law, such as under the Health Insurance Portability and Accountability Act (HIPAA) or per the European Union's Data Protection Directive. For example, a physician may seek to review and evaluate his patient's ECG monitoring data, as securely stored in the secure database **124**. The physician would execute an application program **130** ("Pgm"), such as a post-monitoring ECG analysis program, on a personal computer **129** or other connectable computing device, and, through the application **130**, coordinate access to his patient's EMRs **134** with the patient management program **123**. Other schemes and safeguards to protect and maintain the integrity of patient EMRs **134** are possible.

The wearable monitor **12** can interoperate wirelessly with other wearable physiology and activity sensors **131** and with wearable or mobile communications devices **133**. Wearable physiology and activity sensors **131** encompass a wide range of wirelessly interconnectable devices that measure or monitor data physical to the patient's body, such as heart rate, temperature, blood pressure, and so forth; physical states, such as movement, sleep, footsteps, and the like; and performance, including calories burned or estimated blood glucose level. These devices originate both within the medical community to sense and record traditional medical physiology that could be useful to a physician in arriving at a patient diagnosis or clinical trajectory, as well as from outside the medical community, from, for instance, sports or lifestyle product companies who seek to educate and assist individuals with self-quantifying interests.

Frequently, wearable physiology and activity sensors **131** are capable of wireless interfacing with wearable or mobile communications devices **133**, particularly smart mobile devices, including so-called "smart phones," to download monitoring data either in real-time or in batches. The wearable or mobile communications device **133** executes an application ("App") that can retrieve the data collected by the wearable physiology and activity sensor **131** and evaluate the data to generate information of interest to the wearer, such as an estimation of the effectiveness of the wearer's exercise efforts. Still other wearable or mobile communications device **133** functions on the collected data are possible.

The wearable or mobile communications devices **133** could also serve as a conduit for providing the data collected by the wearable physiology and activity sensor **131** to a server **122**, or, similarly, the wearable physiology and activity sensor **131** could itself directly provide the collected data to the server **122**. The server **122** could then merge the collected data into the wearer's EMRs **134** in the secure database **124**, if appropriate (and permissible), or the server **122** could perform an analysis of the collected data, perhaps based by comparison to a population of like wearers of the wearable physiology and activity sensor **131**. Still other server **122** functions on the collected data are possible.

Finally, the monitor recorder **14** can also be equipped with a wireless transceiver, as further described infra with reference to FIGS. **9** and **10**. Thus, when wireless-enabled, both wearable physiology and activity sensors **131** and wearable or mobile communications devices **133** could wirelessly interface with the monitor recorder **14**, which could either provide data or other information to, or receive data or other information from an interfacing device for relay to a further device, such as the server **122**, analysis, or other purpose. In addition, the monitor recorder **14** could wirelessly interface directly with the server **122**, personal computer **129**, or other computing device connectable over the network **121**, when the monitor recorder **14** is appropriately equipped for interfacing with such devices. Still other types of remote interfacing of the monitor recorder **14** are possible.

During use, the electrode patch **15** is first adhesed to the skin along the sternal midline **16** (or immediately to either side of the sternum **13**). A monitor recorder **14** is then snapped into place on the electrode patch **15** to initiate ECG monitoring. FIG. **4** is a perspective view showing an extended wear electrode patch **15** with a monitor recorder **14** in accordance with one embodiment inserted. The body of the electrode patch **15** is preferably constructed using a flexible backing **20** formed as an elongated strip **21** of wrap knit or similar stretchable material with a narrow longitudinal mid-section **23** evenly tapering inward from both sides. A pair of cut-outs **22** between the distal and proximal

ends of the electrode patch **15** create a narrow longitudinal midsection **23** or "isthmus" and defines an elongated "hourglass"-like shape, when viewed from above.

The electrode patch **15** incorporates features that significantly improve wearability, performance, and patient comfort throughout an extended monitoring period. During wear, the electrode patch **15** is susceptible to pushing, pulling, and torqueing movements, including compressional and torsional forces when the patient bends forward, and tensile and torsional forces when the patient leans backwards. To counter these stress forces, the electrode patch **15** incorporates strain and crimp reliefs, such as described in commonly-assigned U.S. Patent, entitled "Extended Wear Electrocardiography Patch," U.S. Pat. No. 9,545,204, issued Jan. 17, 2017, the disclosure of which is incorporated by reference. In addition, the cut-outs **22** and longitudinal midsection **23** help minimize interference with and discomfort to breast tissue, particularly in women (and gynecomastic men). The cut-outs **22** and longitudinal midsection **23** further allow better conformity of the electrode patch **15** to sternal bowing and to the narrow isthmus of flat skin that can occur along the bottom of the intermammary cleft between the breasts, especially in buxom women. The cut-outs **22** and longitudinal midsection **23** help the electrode patch **15** fit nicely between a pair of female breasts in the intermammary cleft. Still other shapes, cut-outs and conformities to the electrode patch **15** are possible.

The monitor recorder **14** removably and reusably snaps into an electrically non-conductive receptacle **25** during use. The monitor recorder **14** contains electronic circuitry for recording and storing the patient's electrocardiography as sensed via a pair of ECG electrodes provided on the electrode patch **15**, such as described in commonly-assigned U.S. Patent, entitled "Extended Wear Ambulatory Electrocardiography and Physiological Sensor Monitor," U.S. Pat. No. 9,730,593, issued Aug. 15, 2017, the disclosure which is incorporated by reference. The non-conductive receptacle **25** is provided on the top surface of the flexible backing **20** with a retention catch **26** and tension clip **27** molded into the non-conductive receptacle **25** to conformably receive and securely hold the monitor recorder **14** in place.

The monitor recorder **14** includes a sealed housing that snaps into place in the non-conductive receptacle **25**. FIG. **5** is a perspective view showing the monitor recorder **14** of FIG. **4**. The sealed housing **50** of the monitor recorder **14** intentionally has a rounded isosceles trapezoidal-like shape **52**, when viewed from above, such as described in commonly-assigned U.S. Design Patent, entitled "Electrocardiography Monitor," No. D717,955, issued Nov. 18, 2014, the disclosure of which is incorporated by reference. The edges **51** along the top and bottom surfaces are rounded for patient comfort. The sealed housing **50** is approximately 47 mm long, 23 mm wide at the widest point, and 7 mm high, excluding a patient-operable tactile-feedback button **55**. The sealed housing **50** can be molded out of polycarbonate, ABS, or an alloy of those two materials. The button **55** is waterproof and the button's top outer surface is molded silicon rubber or similar soft pliable material. A retention detent **53** and tension detent **54** are molded along the edges of the top surface of the housing **50** to respectively engage the retention catch **26** and the tension clip **27** molded into non-conductive receptacle **25**. Other shapes, features, and conformities of the sealed housing **50** are possible.

The electrode patch **15** is intended to be disposable. The monitor recorder **14**, however, is reusable and can be transferred to successive electrode patches **15** to ensure continuity of monitoring. The placement of the wearable monitor **12** in a location at the sternal midline **16** (or immediately to either side of the sternum **13**) benefits long-term extended wear by removing the requirement that ECG electrodes be continually placed in the same spots on the skin throughout the monitoring period. Instead, the patient is free to place an electrode patch **15** anywhere within the general region of the sternum **13**.

As a result, at any point during ECG monitoring, the patient's skin is able to recover from the wearing of an electrode patch **15**, which increases patient comfort and satisfaction, while the monitor recorder **14** ensures ECG monitoring continuity with minimal effort. A monitor recorder **14** is merely unsnapped from a worn out electrode patch **15**, the worn out electrode patch **15** is removed from the skin, a new electrode patch **15** is adhered to the skin, possibly in a new spot immediately adjacent to the earlier location, and the same monitor recorder **14** is snapped into the new electrode patch **15** to reinitiate and continue the ECG monitoring.

During use, the electrode patch **15** is first adhered to the skin in the sternal region. FIG. **6** is a perspective view showing the extended wear electrode patch **15** of FIG. **4** without a monitor recorder **14** inserted. A flexible circuit **32** is adhered to each end of the flexible backing **20**. A distal circuit trace **33** and a proximal circuit trace (not shown) electrically couple ECG electrodes (not shown) to a pair of electrical pads **34**. The electrical pads **34** are provided within a moisture-resistant seal **35** formed on the bottom surface of the non-conductive receptacle **25**. When the monitor recorder **14** is securely received into the non-conductive receptacle **25**, that is, snapped into place, the electrical pads **34** interface to electrical contacts (not shown) protruding from the bottom surface of the monitor recorder **14**, and the moisture-resistant seal **35** enables the monitor recorder **14** to be worn at all times, even during bathing or other activities that could expose the monitor recorder **14** to moisture.

In addition, a battery compartment **36** is formed on the bottom surface of the non-conductive receptacle **25**, and a pair of battery leads (not shown) electrically interface the battery to another pair of the electrical pads **34**. The battery contained within the battery compartment **35** can be replaceable, rechargeable or disposable.

The monitor recorder **14** draws power externally from the battery provided in the non-conductive receptacle **25**, thereby uniquely obviating the need for the monitor recorder **14** to carry a dedicated power source. FIG. **7** is a bottom plan view of the monitor recorder **14** of FIG. **4**. A cavity **58** is formed on the bottom surface of the sealed housing **50** to accommodate the upward projection of the battery compartment **36** from the bottom surface of the non-conductive receptacle **25**, when the monitor recorder **14** is secured in place on the non-conductive receptacle **25**. A set of electrical contacts **56** protrude from the bottom surface of the sealed housing **50** and are arranged in alignment with the electrical pads **34** provided on the bottom surface of the non-conductive receptacle **25** to establish electrical connections between the electrode patch **15** and the monitor recorder **14**. In addition, a seal coupling **57** circumferentially surrounds the set of electrical contacts **56** and securely mates with the moisture-resistant seal **35** formed on the bottom surface of the non-conductive receptacle **25**.

The placement of the flexible backing **20** on the sternal midline **16** (or immediately to either side of the sternum **13**) also helps to minimize the side-to-side movement of the wearable monitor **12** in the left- and right-handed directions during wear. To counter the dislodgment of the flexible backing **20** due to compressional and torsional forces, a

layer of non-irritating adhesive, such as hydrocolloid, is provided at least partially on the underside, or contact, surface of the flexible backing **20**, but only on the distal end **30** and the proximal end **31**. As a result, the underside, or contact surface of the longitudinal midsection **23** does not have an adhesive layer and remains free to move relative to the skin. Thus, the longitudinal midsection **23** forms a crimp relief that respectively facilitates compression and twisting of the flexible backing **20** in response to compressional and torsional forces. Other forms of flexible backing crimp reliefs are possible.

Unlike the flexible backing **20**, the flexible circuit **32** is only able to bend and cannot stretch in a planar direction. The flexible circuit **32** can be provided either above or below the flexible backing **20**. FIG. **8** is a top view showing the flexible circuit **32** of the extended wear electrode patch **15** of FIG. **4** when mounted above the flexible backing **20**. A distal ECG electrode **38** and proximal ECG electrode **39** are respectively coupled to the distal and proximal ends of the flexible circuit **32**. A strain relief **40** is defined in the flexible circuit **32** at a location that is partially underneath the battery compartment **36** when the flexible circuit **32** is affixed to the flexible backing **20**. The strain relief **40** is laterally extendable to counter dislodgment of the ECG electrodes **38**, **39** due to tensile and torsional forces. A pair of strain relief cutouts **41** partially extend transversely from each opposite side of the flexible circuit **32** and continue longitudinally towards each other to define in 'S'-shaped pattern, when viewed from above. The strain relief respectively facilitates longitudinal extension and twisting of the flexible circuit **32** in response to tensile and torsional forces. Other forms of circuit board strain relief are possible.

ECG monitoring and other functions performed by the monitor recorder **14** are provided through a micro controlled architecture. FIG. **9** is a functional block diagram showing the component architecture of the circuitry **60** of the monitor recorder **14** of FIG. **4**. The circuitry **60** is externally powered through a battery provided in the non-conductive receptacle **25** (shown in FIG. **6**). Both power and raw ECG signals, which originate in the pair of ECG electrodes **38**, **39** (shown in FIG. **8**) on the distal and proximal ends of the electrode patch **15**, are received through an external connector **65** that mates with a corresponding physical connector on the electrode patch **15**. The external connector **65** includes the set of electrical contacts **56** that protrude from the bottom surface of the sealed housing **50** and which physically and electrically interface with the set of pads **34** provided on the bottom surface of the non-conductive receptacle **25**. The external connector includes electrical contacts **56** for data download, microcontroller communications, power, analog inputs, and a peripheral expansion port. The arrangement of the pins on the electrical connector **65** of the monitor recorder **14** and the device into which the monitor recorder **14** is attached, whether an electrode patch **15** or download station (not shown), follow the same electrical pin assignment convention to facilitate interoperability. The external connector **65** also serves as a physical interface to a download station that permits the retrieval of stored ECG monitoring data, communication with the monitor recorder **14**, and performance of other functions.

Operation of the circuitry **60** of the monitor recorder **14** is managed by a microcontroller **61**. The micro-controller **61** includes a program memory unit containing internal flash memory that is readable and writeable. The internal flash memory can also be programmed externally. The microcontroller **61** draws power externally from the battery provided on the electrode patch **15** via a pair of the electrical contacts **56**. The microcontroller **61** connects to the ECG front end circuit **63** that measures raw cutaneous electrical signals and generates an analog ECG signal representative of the electrical activity of the patient's heart over time.

The circuitry **60** of the monitor recorder **14** also includes a flash memory **62**, which the micro-controller **61** uses for storing ECG monitoring data and other physiology and information. The flash memory **62** also draws power externally from the battery provided on the electrode patch **15** via a pair of the electrical contacts **56**. Data is stored in a serial flash memory circuit, which supports read, erase and program operations over a communications bus. The flash memory **62** enables the microcontroller **61** to store digitized ECG data. The communications bus further enables the flash memory **62** to be directly accessed externally over the external connector **65** when the monitor recorder **14** is interfaced to a download station.

The circuitry **60** of the monitor recorder **14** further includes an actigraphy sensor **64** implemented as a 3-axis accelerometer. The accelerometer may be configured to generate interrupt signals to the microcontroller **61** by independent initial wake up and free fall events, as well as by device position. In addition, the actigraphy provided by the accelerometer can be used during post-monitoring analysis to correct the orientation of the monitor recorder **14** if, for instance, the monitor recorder **14** has been inadvertently installed upside down, that is, with the monitor recorder **14** oriented on the electrode patch **15** towards the patient's feet, as well as for other event occurrence analyses, such as described in commonly-assigned U.S. Pat. No. 9,737,224, issued Aug. 22, 2017, the disclosure of which is incorporated by reference.

The circuitry **60** of the monitor recorder **14** includes a wireless transceiver **69** that can provides wireless interfacing capabilities. The wireless transceiver **69** also draws power externally from the battery provided on the electrode patch **15** via a pair of the electrical contacts **56**. The wireless transceiver **69** can be implemented using one or more forms of wireless communications, including the IEEE 802.11 computer communications standard, that is Wi-Fi; the 4G mobile phone mobile communications standard; the Bluetooth data exchange standard; or other wireless communications or data exchange standards and protocols. The type of wireless interfacing capability could limit the range of interoperability of the monitor recorder **14**; for instance, Bluetooth-based implementations are designed for low power consumption with a short communications range.

The microcontroller **61** includes an expansion port that also utilizes the communications bus. External devices, separately drawing power externally from the battery provided on the electrode patch **15** or other source, can interface to the microcontroller **61** over the expansion port in half duplex mode. For instance, an external physiology sensor can be provided as part of the circuitry **60** of the monitor recorder **14**, or can be provided on the electrode patch **15** with communication with the micro-controller **61** provided over one of the electrical contacts **56**. The physiology sensor can include an SpO_2 sensor, blood pressure sensor, temperature sensor, respiratory rate sensor, glucose sensor, airflow sensor, volumetric pressure sensing, or other types of sensor or telemetric input sources. For instance, the integration of an airflow sensor is described in commonly-assigned U.S. Pat. No. 9,364,155, issued Jun. 14, 2016, the disclosure which is incorporated by reference.

Finally, the circuitry **60** of the monitor recorder **14** includes patient-interfaceable components, including a tactile feedback button **66**, which a patient can press to mark

events or to perform other functions, and a buzzer **67**, such as a speaker, magnetic resonator or piezoelectric buzzer. The buzzer **67** can be used by the microcontroller **61** to output feedback to a patient such as to confirm power up and initiation of ECG monitoring. Still other components as part of the circuitry **60** of the monitor recorder **14** are possible.

While the monitor recorder **14** operates under micro control, most of the electrical components of the electrode patch **15** operate passively. FIG. **10** is a functional block diagram showing the circuitry **70** of the extended wear electrode patch **15** of FIG. **4**. The circuitry **70** of the electrode patch **15** is electrically coupled with the circuitry **60** of the monitor recorder **14** through an external connector **74**. The external connector **74** is terminated through the set of pads **34** provided on the bottom of the non-conductive receptacle **25**, which electrically mate to corresponding electrical contacts **56** protruding from the bottom surface of the sealed housing **50** to electrically interface the monitor recorder **14** to the electrode patch **15**.

The circuitry **70** of the electrode patch **15** performs three primary functions. First, a battery **71** is provided in a battery compartment formed on the bottom surface of the non-conductive receptacle **25**. The battery **71** is electrically interfaced to the circuitry **60** of the monitor recorder **14** as a source of external power. The unique provisioning of the battery **71** on the electrode patch **15** provides several advantages. First, the locating of the battery **71** physically on the electrode patch **15** lowers the center of gravity of the overall wearable monitor **12** and thereby helps to minimize shear forces and the effects of movements of the patient and clothing. Moreover, the housing **50** of the monitor recorder **14** is sealed against moisture and providing power externally avoids having to either periodically open the housing **50** for the battery replacement, which also creates the potential for moisture intrusion and human error, or to recharge the battery, which can potentially take the monitor recorder **14** off line for hours at a time. In addition, the electrode patch **15** is intended to be disposable, while the monitor recorder **14** is a reusable component. Each time that the electrode patch **15** is replaced, a fresh battery is provided for the use of the monitor recorder **14**, which enhances ECG monitoring performance quality and duration of use. Finally, the architecture of the monitor recorder **14** is open, in that other physiology sensors or components can be added by virtue of the expansion port of the microcontroller **61**. Requiring those additional sensors or components to draw power from a source external to the monitor recorder **14** keeps power considerations independent of the monitor recorder **14**. Thus, a battery of higher capacity could be introduced when needed to support the additional sensors or components without effecting the monitor recorders circuitry **60**.

Second, the pair of ECG electrodes **38**, **39** respectively provided on the distal and proximal ends of the flexible circuit **32** are electrically coupled to the set of pads **34** provided on the bottom of the non-conductive receptacle **25** by way of their respective circuit traces **33**, **37**. The signal ECG electrode **39** includes a protection circuit **72**, which is an inline resistor that protects the patient from excessive leakage current.

Last, in a further embodiment, the circuitry **70** of the electrode patch **15** includes a cryptographic circuit **73** to authenticate an electrode patch **15** for use with a monitor recorder **14**. The cryptographic circuit **73** includes a device capable of secure authentication and validation. The cryptographic device **73** ensures that only genuine, non-expired, safe, and authenticated electrode patches **15** are permitted to provide monitoring data to a monitor recorder **14**, such as described in commonly-assigned U.S. Pat. No. 9,655,538, issued May 23, 2017, the disclosure which is incorporated by reference.

In a further embodiment, the circuitry **70** of the electrode patch **15** includes a wireless transceiver **75**, in lieu the including of the wireless transceiver **69** in the circuitry **60** of the monitor recorder **14**, which interfaces with the microcontroller **61** over the microcontroller's expansion port via the external connector **74**.

The monitor recorder **14** continuously monitors the patient's heart rate and physiology. FIG. **11** is a flow diagram showing a monitor recorder-implemented method **100** for monitoring ECG data for use in the monitor recorder **14** of FIG. **4**. Initially, upon being connected to the set of pads **34** provided with the non-conductive receptacle **25** when the monitor recorder **14** is snapped into place, the microcontroller **61** executes a power up sequence (step **101**). During the power up sequence, the voltage of the battery **71** is checked, the state of the flash memory **62** is confirmed, both in terms of operability check and available capacity, and microcontroller operation is diagnostically confirmed. In a further embodiment, an authentication procedure between the microcontroller **61** and the electrode patch **15** are also performed.

Following satisfactory completion of the power up sequence, an iterative processing loop (steps **102**-**109**) is continually executed by the microcontroller **61**. During each iteration (step **102**) of the processing loop, the ECG frontend **63** (shown in FIG. **9**) continually senses the cutaneous ECG electrical signals (step **103**) via the ECG electrodes **38**, **29** and is optimized to maintain the integrity of the P-wave. A sample of the ECG signal is read (step **104**) by the microcontroller **61** by sampling the analog ECG signal output front end **63**. FIG. **12** is a graph showing, by way of example, a typical ECG waveform **110**. The x-axis represents time in approximate units of tenths of a second. The y-axis represents cutaneous electrical signal strength in approximate units of millivolts. The P-wave **111** has a smooth, normally upward, that is, positive, waveform that indicates atrial depolarization. The QRS complex usually begins with the downward deflection of a Q wave **112**, followed by a larger upward deflection of an R-wave **113**, and terminated with a downward waveform of the S wave **114**, collectively representative of ventricular depolarization. The T wave **115** is normally a modest upward waveform, representative of ventricular depolarization, while the U wave **116**, often not directly observable, indicates the recovery period of the Purkinje conduction fibers.

Sampling of the R-to-R interval enables heart rate information derivation. For instance, the R-to-R interval represents the ventricular rate and rhythm, while the P-to-P interval represents the atrial rate and rhythm. Importantly, the PR interval is indicative of atrioventricular (AV) conduction time and abnormalities in the PR interval can reveal underlying heart disorders, thus representing another reason why the P-wave quality achievable by the extended wear ambulatory electrocardiography and physiological sensor monitor described herein is medically unique and important. The long-term observation of these ECG indicia, as provided through extended wear of the wearable monitor **12**, provides valuable insights to the patient's cardiac function and overall well-being.

Each sampled ECG signal, in quantized and digitized form, is temporarily staged in buffer (step **105**), pending compression preparatory to storage in the flash memory **62** (step **106**). Following compression, the compressed ECG digitized sample is again buffered (step **107**), then written to

the flash memory **62** (step **108**) using the communications bus. Processing continues (step **109**), so long as the monitoring recorder **14** remains connected to the electrode patch **15** (and storage space remains available in the flash memory **62**), after which the processing loop is exited and execution terminates. Still other operations and steps are possible.

In a further embodiment, the monitor recorder **14** also continuously receives data from wearable physiology and activity sensors **131** and wearable or mobile communications devices **133** (shown in FIG. **3**). The data is received in a conceptually-separate execution thread as part of the iterative processing loop (steps **102**-**109**) continually executed by the microcontroller **61**. During each iteration (step **102**) of the processing loop, if wireless data is available (step **140**), a sample of the wireless is read (step **141**) by the microcontroller **61** and, if necessary, converted into a digital signal by the onboard ADC of the microcontroller **61**. Each wireless data sample, in quantized and digitized form, is temporarily staged in buffer (step **142**), pending compression preparatory to storage in the flash memory **62** (step **143**). Following compression, the compressed wireless data sample is again buffered (step **144**), then written to the flash memory **62** (step **145**) using the communications bus. Processing continues (step **109**), so long as the monitoring recorder **14** remains connected to the electrode patch **15** (and storage space remains available in the flash memory **62**), after which the processing loop is exited and execution terminates. Still other operations and steps are possible.

The monitor recorder **14** stores ECG data and other information in the flash memory **62** (shown in FIG. **9**) using a proprietary format that includes data compression. As a result, data retrieved from a monitor recorder **14** must first be converted into a format suitable for use by third party post-monitoring analysis software. FIG. **13** is a flow diagram showing a method **150** for offloading and converting ECG and other physiological data from an extended wear electrocardiography and physiological sensor monitor **12** in accordance with one embodiment. The method **150** can be implemented in software and execution of the software can be performed on a download station **125**, which could be a programmer or other device, or a computer system, including a server **122** or personal computer **129**, such as further described supra with reference to FIG. **3**, as a series of process or method modules or steps. For convenience, the method **150** will be described in the context of being performed by a personal computer **136** or other connectable computing device (shown in FIG. **3**) as middleware that converts ECG data and other information into a format suitable for use by a third-party post-monitoring analysis program. Execution of the method **150** by a computer system would be analogous mutatis mutandis.

Initially, the download station **125** is connected to the monitor recorder **14** (step **151**), such as by physically interfacing to a set of terminals **128** on a paired receptacle **127** or by wireless connection, if available. The data stored on the monitor recorder **14**, including ECG and physiological monitoring data, other recorded data, and other information are retrieved (step **152**) over a hard link **135** using a control program **137** ("Ctl") or analogous application executing on a personal computer **136** or other connectable computing device.

The data retrieved from the monitor recorder **14** is in a proprietary storage format and each datum of recorded ECG monitoring data, as well as any other physiological data or other information, must be converted, so that the data can be used by a third-party post-monitoring analysis program. Each datum of ECG monitoring data is converted by the middleware (steps **153**-**159**) in an iterative processing loop. During each iteration (step **153**), the ECG datum is read (step **154**) and, if necessary, the gain of the ECG signal is adjusted (step **155**) to compensate, for instance, for relocation or replacement of the electrode patch **15** during the monitoring period.

In addition, depending upon the configuration of the wearable monitor **12**, other physiological data (or other information), including patient events, such as a fall, peak activity level, sleep detection, Detection of patient activity levels and states, and so on, may be recorded along with the ECG monitoring data. For instance, actigraphy data may have been sampled by the actigraphy sensor **64** based on a sensed event occurrence, such as a sudden change in orientation due to the patient taking a fall. In response, the monitor recorder **14** will embed the actigraphy data samples into the stream of data, including ECG monitoring data, that is recorded to the flash memory **62** by the micro-controller **61**. Post-monitoring, the actigraphy data is temporally matched to the ECG data to provide the proper physiological context to the sensed event occurrence. As a result, the three-axis actigraphy signal is turned into an actionable event occurrence that is provided, through conversion by the middleware, to third party post-monitoring analysis programs, along with the ECG recordings contemporaneous to the event occurrence. Other types of processing of the other physiological data (or other information) are possible.

Thus, during execution of the middleware, any other physiological data (or other information) that has been embedded into the recorded ECG monitoring data is read (step **156**) and time-correlated to the time frame of the ECG signals that occurred at the time that the other physiological data (or other information) was noted (step **157**). Finally, the ECG datum, signal gain adjusted, if appropriate, and other physiological data, if applicable and as time-correlated, are stored in a format suitable to the backend software (step **158**) used in post-monitoring analysis.

In a further embodiment, the other physiological data, if apropos, is embedded within an unused ECG track. For example, the SCP-ENG standard allows multiple ECG channels to be recorded into a single ECG record. The monitor recorder **14**, though, only senses one ECG channel. The other physiological data can be stored into an additional ECG channel, which would otherwise be zero-padded or altogether omitted. The backend software would then be able to read the other physiological data in context with the single channel of ECG monitoring data recorded by the monitor recorder **14**, provided the backend software implemented changes necessary to interpret the other physiological data. Still other forms of embedding of the other physiological data with formatted ECG monitoring data, or of providing the other physiological data in a separate manner, are possible.

Processing continues (step **159**) for each remaining ECG datum, after which the processing loop is exited and execution terminates. Still other operations and steps are possible.

While the invention has been particularly shown and described as referenced to the embodiments thereof, those skilled in the art will understand that the foregoing and other changes in form and detail may be made therein without departing from the spirit and scope.

What is claimed is:

1. A wearable electrocardiography monitoring device, comprising:

a flexible backing including a strip comprising:

a first face and a second face, wherein a portion of the first face is covered in adhesive to adhere the strip to skin of a patient,

a first end section,

a second end section opposite the first end section, and

a mid-section between the first end section and the second end section, wherein the mid-section is narrower than the first end section and the second end section;

a flexible circuit mounted to the second face of the strip, the flexible circuit comprising a first circuit trace and a second circuit trace;

a first electrocardiographic electrode and a second electrocardiographic electrode, wherein the first electrocardiographic electrode and the second electrocardiographic electrode are configured to sense electrocardiographic signals, wherein the first electrocardiographic electrode and the second electrocardiographic electrode are coupled to the flexible circuit, wherein the first electrocardiographic electrode is conductively exposed at the first face along the first end section of the strip, wherein the second electrocardiographic electrode is conductively exposed at the first face along the second end section of the strip, wherein the first circuit trace is electrically coupled to the first electrocardiographic electrode, wherein the second circuit trace is electrically coupled to the second electrocardiographic electrode, and wherein the first electrocardiographic electrode includes an inline resistor;

a battery vertically aligned with a sealed housing, wherein the sealed housing includes rounded edges on a top surface, wherein the sealed housing is coupled to the flexible backing, and wherein the sealed housing includes a processor, wherein the processor is electrically coupled to the first electrocardiographic electrode, the second electrocardiographic electrode, and the battery, wherein the processor is configured to process the electrocardiographic signals sensed via the first electrocardiographic electrode and the second electrocardiographic electrode; and

a wireless transceiver, wherein the wireless transceiver draws power from the battery.

2. The wearable electrocardiography monitoring device of claim **1**, wherein the mid-section comprises a first edge parallel to a second edge.

3. The wearable electrocardiography monitoring device of claim **1**, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.

4. The wearable electrocardiography monitoring device of claim **1**, wherein the electrocardiographic signals are converted to a different format.

5. The wearable electrocardiography monitoring device of claim **4**, wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.

6. The wearable electrocardiography monitoring device of claim **1**, wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.

7. The wearable electrocardiography monitoring device of claim **1**, wherein the battery is vertically aligned with the wireless transceiver.

8. A wearable electrocardiography monitoring device, comprising:

a flexible backing including a strip comprising:

a first face and a second face, wherein a portion of the first face is covered in adhesive to adhere the strip to skin of a patient,

a first end section,

a second end section opposite the first end section, and

a mid-section between the first end section and the second end section, wherein the mid-section is narrower than the first end section and the second end section, and wherein the mid-section comprises a first edge parallel to a second edge;

a flexible circuit mounted to the second face of the strip, the flexible circuit comprising a first circuit trace and a second circuit trace;

a first electrocardiographic electrode and a second electrocardiographic electrode, wherein the first electrocardiographic electrode and the second electrocardiographic electrode are configured to sense electrocardiographic signals, wherein the first electrocardiographic electrode and the second electrocardiographic electrode are coupled to the flexible circuit, wherein the first electrocardiographic electrode is conductively exposed at the first face along the first end section of the strip, wherein the second electrocardiographic electrode is conductively exposed at the first face along the second end section of the strip, wherein the first circuit trace is electrically coupled to the first electrocardiographic electrode, wherein the second circuit trace is electrically coupled to the second electrocardiographic electrode, and wherein the first electrocardiographic electrode includes an inline resistor;

a battery;

a wireless transceiver, wherein the wireless transceiver draws power from the battery; and

a sealed housing having rounded edges on a top surface, wherein the sealed housing is coupled to the flexible backing, and wherein the sealed housing includes a processor, wherein the processor is electrically coupled to the first electrocardiographic electrode, the second electrocardiographic electrode, and the battery, wherein the processor is configured to process the electrocardiographic signals sensed via the first electrocardiographic electrode and the second electrocardiographic electrode.

9. The wearable electrocardiography monitoring device of claim **8**, wherein the battery is vertically aligned with the sealed housing.

10. The wearable electrocardiography monitoring device of claim **8**, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.

11. The wearable electrocardiography monitoring device of claim **8**, wherein the electrocardiographic signals are converted to a different format.

12. The wearable electrocardiography monitoring device of claim **11**, wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.

13. The wearable electrocardiography monitoring device of claim **8**, wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.

14. The wearable electrocardiography monitoring device of claim **8**, wherein the battery is vertically aligned with the wireless transceiver.

15. A wearable electrocardiography monitoring device, comprising:

a flexible backing including a strip comprising:

a first face and a second face, wherein a portion of the first face is covered in adhesive to adhere the strip to skin of a patient,

a first end section,

a second end section opposite the first end section, and

a mid-section between the first end section and the second end section, wherein the mid-section is narrower than the first end section and the second end section, and wherein the mid-section comprises a first edge parallel to a second edge;

a flexible circuit mounted to the second face of the strip, the flexible circuit comprising a first circuit trace and a second circuit trace;

a first electrocardiographic electrode and a second electrocardiographic electrode, wherein the first electrocardiographic electrode and the second electrocardiographic electrode are configured to sense electrocardiographic signals, wherein the first electrocardiographic electrode and the second electrocardiographic electrode are coupled to the flexible circuit, wherein the first electrocardiographic electrode is conductively exposed at the first face along the first end section of the strip, wherein the second electrocardiographic electrode is conductively exposed at the first face along the second end section of the strip, wherein the first circuit trace is electrically coupled to the first electrocardiographic electrode, wherein the second circuit trace is electrically coupled to the second electrocardiographic electrode, and wherein the first electrocardiographic electrode includes an inline resistor;

a battery vertically aligned with a sealed housing, wherein the sealed housing includes rounded edges on a top surface, wherein the sealed housing is coupled to the flexible backing, and wherein the sealed housing includes a processor, wherein the processor is electrically coupled to the first electrocardiographic electrode, the second electrocardiographic electrode, and the battery, wherein the processor is configured to process the electrocardiographic signals sensed via the first electrocardiographic electrode and the second electrocardiographic electrode; and

a wireless transceiver, wherein the wireless transceiver draws power from the battery.

16. The wearable electrocardiography monitoring device of claim **15**, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.

17. The wearable electrocardiography monitoring device of claim **15**, wherein the electrocardiographic signals are converted to a different format.

18. The wearable electrocardiography monitoring device of claim **17**, wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.

19. The wearable electrocardiography monitoring device of claim **15**, wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.

20. The wearable electrocardiography monitoring device of claim **15**, wherein the battery is vertically aligned with the wireless transceiver.

21. The wearable electrocardiography monitoring device of claim **20**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format,

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format,

wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only, and

wherein the battery is vertically aligned with the wireless transceiver.

22. The wearable electrocardiography monitoring device of claim **20**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to a different format,

wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only, and

wherein the battery is vertically aligned with the wireless transceiver.

23. The wearable electrocardiography monitoring device of claim **20**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format,

wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only, and

wherein the battery is vertically aligned with the wireless transceiver.

24. The wearable electrocardiography monitoring device of claim **20**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format,

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format, and

wherein the battery is vertically aligned with the wireless transceiver.

25. The wearable electrocardiography monitoring device of claim **20**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format,

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format, and

wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.

26. The wearable electrocardiography monitoring device of claim **20**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format, and

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.

27. The wearable electrocardiography monitoring device of claim **20**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format, and

wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.

28. The wearable electrocardiography monitoring device of claim **20**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format, and

wherein the battery is vertically aligned with the wireless transceiver.

29. The wearable electrocardiography monitoring device of claim **20**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to a different format, and

wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.

30. The wearable electrocardiography monitoring device of claim **20**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to a different format, and

wherein the battery is vertically aligned with the wireless transceiver.

* * * * *

US012171562B1

(12) **United States Patent**
Felix et al.

(10) **Patent No.: US 12,171,562 B1**
(45) **Date of Patent: *Dec. 24, 2024**

(54) **ELECTROCARDIOGRAMY PATCH**

(71) Applicant: **Bardy Diagnostics, Inc.**, Bellevue, WA (US)

(72) Inventors: **Jason Felix**, Vashon Island, WA (US); **Jon Mikalson Bishay**, Seattle, WA (US); **Gust H. Bardy**, Carnation, WA (US)

(73) Assignee: **Bardy Diagnostics, Inc.**, Bellevue, WA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **18/821,409**

(22) Filed: **Aug. 30, 2024**

Related U.S. Application Data

(63) Continuation of application No. 18/647,762, filed on Apr. 26, 2024, now Pat. No. 12,089,943, which is a (Continued)

(51) **Int. Cl.**
A61B 5/335 (2021.01)
A61B 5/00 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 5/335*** (2021.01); ***A61B 5/0006*** (2013.01); ***A61B 5/0022*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 2560/0214; A61B 2560/0443; A61B 5/0006; A61B 5/0022; A61B 5/02055;
(Continued)

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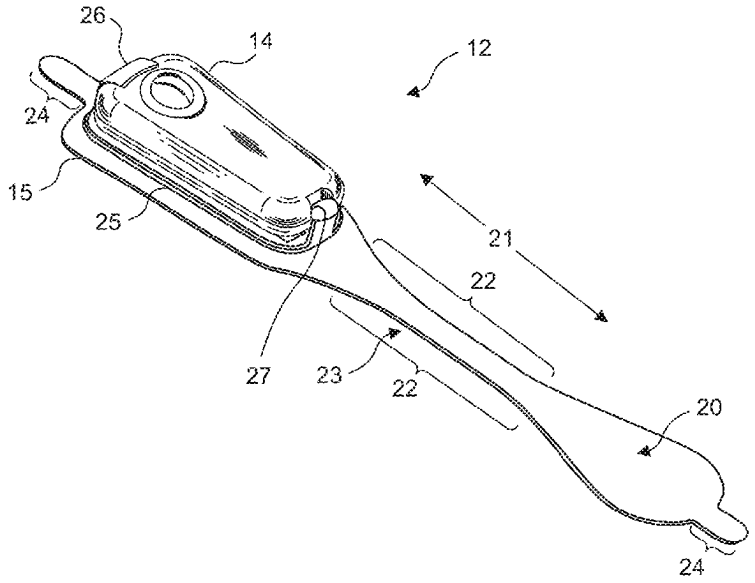
Primary Examiner — George Manuel
(74) *Attorney, Agent, or Firm* — K&L Gates LLP

(57) **ABSTRACT**

An apparatus is provided. A strip has first and second end sections, and a first face and second face. Two electrocardiographic electrodes are provided on the strip with one of the electrocardiographic electrodes provided on the first face of the first end section of the strip and another of the electrocardiographic electrodes positioned on the first face on the second end section of the strip. A flexible circuit is mounted to the second face of the strip and includes a circuit trace electrically coupled to each of the electrocardiographic electrodes. The apparatus includes a wireless transceiver and a battery.

30 Claims, 8 Drawing Sheets



Related U.S. Application Data

continuation of application No. 18/353,398, filed on Jul. 17, 2023, which is a continuation of application No. 17/946,933, filed on Sep. 16, 2022, now Pat. No. 11,723,575, which is a continuation of application No. 17/367,476, filed on Jul. 5, 2021, now Pat. No. 11,445,967, which is a continuation of application No. 17/119,945, filed on Dec. 11, 2020, now Pat. No. 11,051,743, which is a continuation of application No. 16/241,929, filed on Jan. 7, 2019, now Pat. No. 10,888,239, which is a continuation of application No. 15/818,437, filed on Nov. 20, 2017, now Pat. No. 10,172,534, which is a continuation of application No. 15/256,266, filed on Sep. 2, 2016, now Pat. No. 9,820,665, which is a continuation of application No. 14/082,071, filed on Nov. 15, 2013, now Pat. No. 9,433,367, which is a continuation-in-part of application No. 14/080,717, filed on Nov. 14, 2013, now Pat. No. 9,545,204, and a continuation-in-part of application No. 14/080,725, filed on Nov. 14, 2013, now Pat. No. 9,730,593.

(60) Provisional application No. 61/882,403, filed on Sep. 25, 2013.

(51) **Int. Cl.**

A61B 5/0205	(2006.01)
A61B 5/145	(2006.01)
A61B 5/259	(2021.01)
A61B 5/282	(2021.01)
G16H 40/67	(2018.01)
A61B 5/021	(2006.01)
A61B 5/03	(2006.01)
A61B 5/08	(2006.01)
A61B 5/087	(2006.01)
A61B 5/11	(2006.01)
A61B 5/1455	(2006.01)
A61B 5/349	(2021.01)

(52) **U.S. Cl.**

CPC ***A61B 5/02055*** (2013.01); ***A61B 5/14532*** (2013.01); ***A61B 5/14542*** (2013.01); ***A61B 5/259*** (2021.01); ***A61B 5/282*** (2021.01); ***A61B 5/6823*** (2013.01); ***A61B 5/6833*** (2013.01); ***A61B 5/7405*** (2013.01); ***A61B 5/7455*** (2013.01); ***A61B 5/7475*** (2013.01); ***G16H 40/67*** (2018.01); *A61B 5/021* (2013.01); *A61B 5/03* (2013.01); *A61B 5/0816* (2013.01); *A61B 5/087* (2013.01); *A61B 5/1118* (2013.01); *A61B 5/14551* (2013.01); *A61B 5/349* (2021.01); *A61B 2560/0214* (2013.01); *A61B 2560/0443* (2013.01)

(58) **Field of Classification Search**

CPC A61B 5/021; A61B 5/03; A61B 5/0816; A61B 5/087; A61B 5/1118; A61B 5/14532; A61B 5/14542; A61B 5/14551; A61B 5/259; A61B 5/282; A61B 5/335; A61B 5/349; A61B 5/6823; A61B 5/6833; A61B 5/7405; A61B 5/7455; A61B 5/7475; G16H 40/63; G16H 40/67

See application file for complete search history.

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Chart A-3 Invalidity Contentions: U.S. Pat. No. 11,051,743; Case No. 22-351-CJB (Delaware); Invalidity of U.S. Pat. No. 11,051,743 by U.S. Pat. No. 10,327,660 ("Gallego"); Oct. 25, 2023; 12 pages.

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Chart A-4 Invalidity Contentions: U.S. Pat. No. 11,445,967; Case No. 22-351-CJB (Delaware); Invalidity of U.S. Pat. No. 11,445,967 by U.S. Pat. Pub. No. 2011/0077497 ("Oster"); Oct. 25, 2023; 6 pages.

Chart A-5 Invalidity Contentions: U.S. Pat. No. 11,051,743; Case No. 22-351-CJB (Delaware); Invalidity of U.S. Pat. No. 11,051,743 by U.S. Pat. No. 10,413,251 ("Golda"); Oct. 25, 2023; 11 pages.

Chart A-6 Invalidity Contentions: U.S. Pat. No. 11,051,743; Case No. 22-351-CJB (Delaware); Invalidity of U.S. Pat. No. 11,051,743 by U.S. Pat. No. 9,669,212 ("Mueller"); Oct. 25, 2023; 11 pages.

Chart A-7 Invalidity Contentions: U.S. Pat. No. 11,051,743; Case No. 22-351-CJB (Delaware); Invalidity of U.S. Pat. No. 11,051,743 by U.S. Pat. No. 7,206,630 ("Tarler"); Oct. 25, 2023; 12 pages.

Chart A-8 Invalidity Contentions: U.S. Pat. No. 11,051,743; Case No. 22-351-CJB (Delaware); Invalidity of U.S. Pat. No. 11,051,743 by WO 2008/005015 ("Shennib"); Oct. 25, 2023; 12 pages.

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Chart AA-1 Invalidity Contentions: U.S. Pat. No. 11,445,967; Case No. 22-351-CJB (Delaware); Invalidity of U.S. Pat. No. 11,445,967 by International Publication No. WO 2010/104952 to Mazar ("Mazar"); Oct. 25, 2023; 13 pages.

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Chart AA-9 Invalidity Contentions: U.S. Pat. No. 11,445,967; Case No. 22-351-CJB (Delaware); Invalidity of U.S. Pat. No. 11,445,967 by U.S. Pat. Pub. No. 2011/0009729 ("Shin"); Oct. 25, 2023; 6 pages.

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Fig. 1.

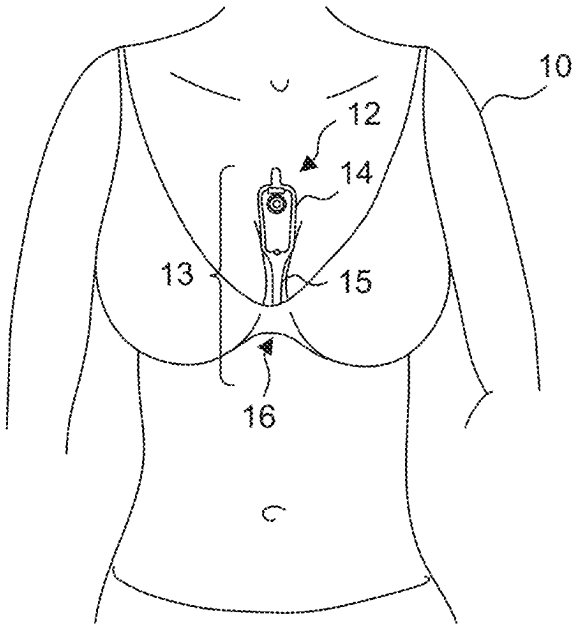

Fig. 2.

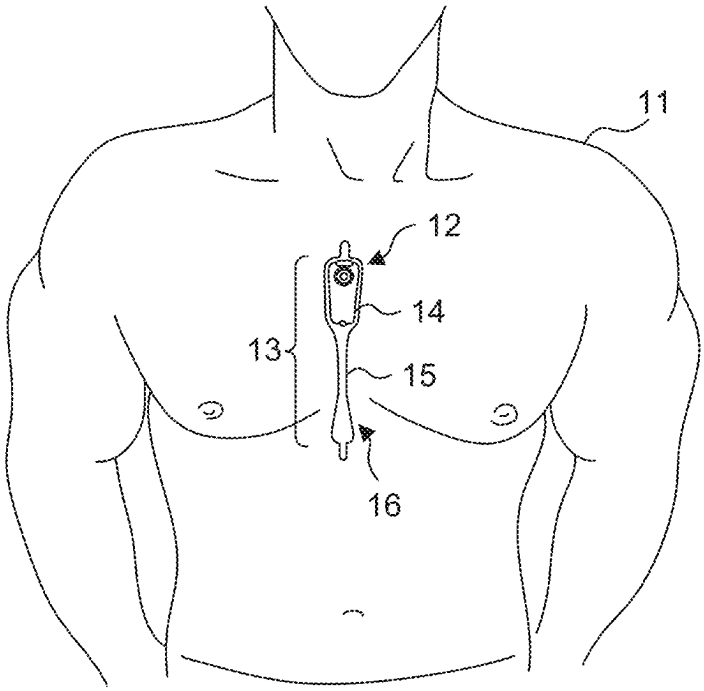

Fig. 3.

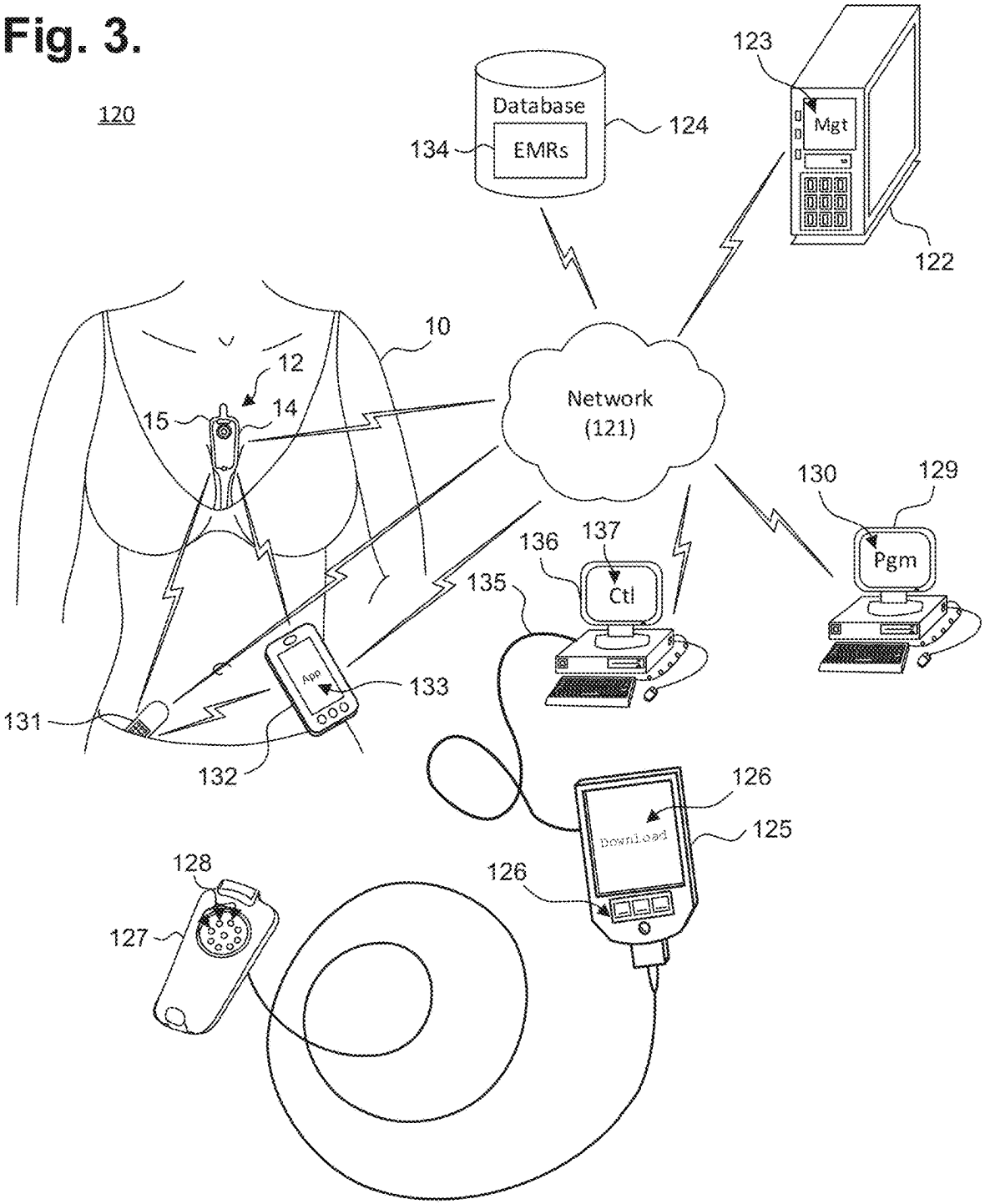
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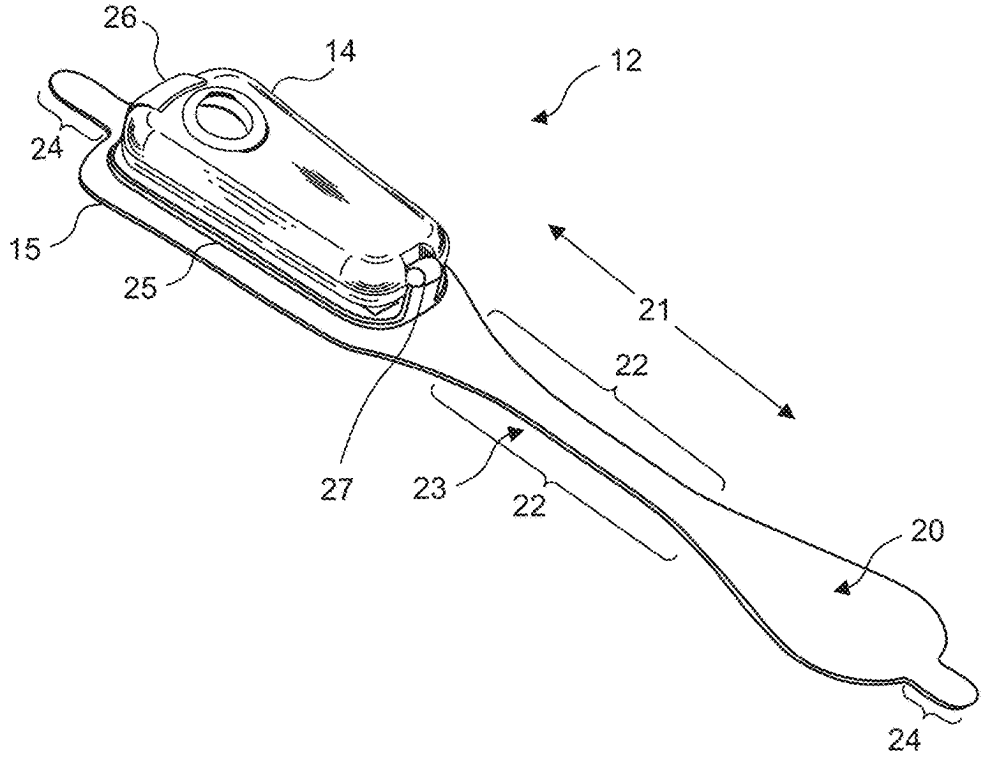
Fig. 4.



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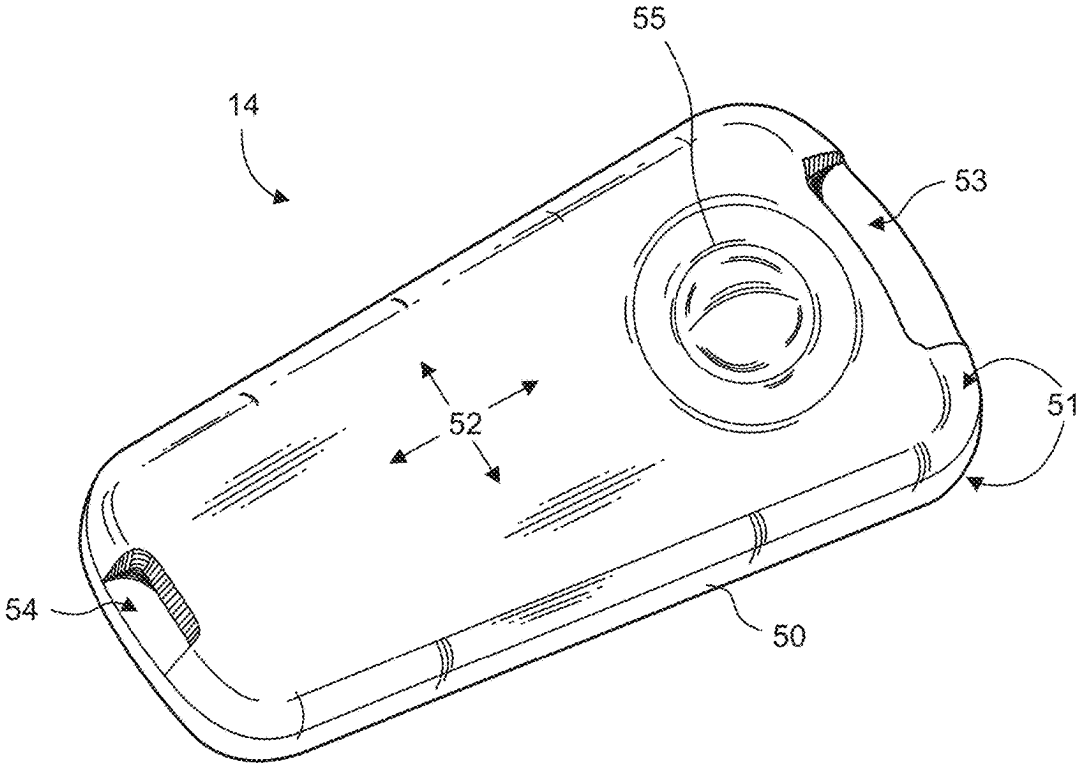

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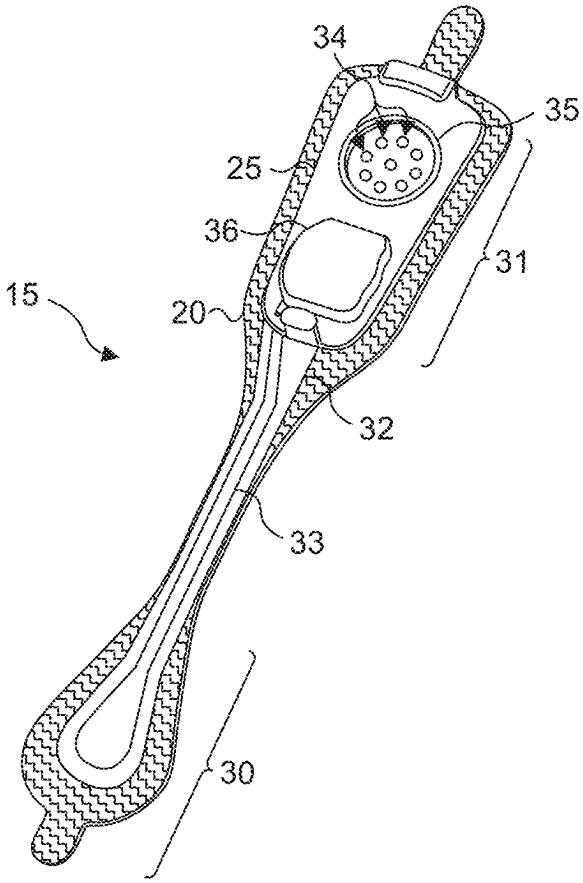

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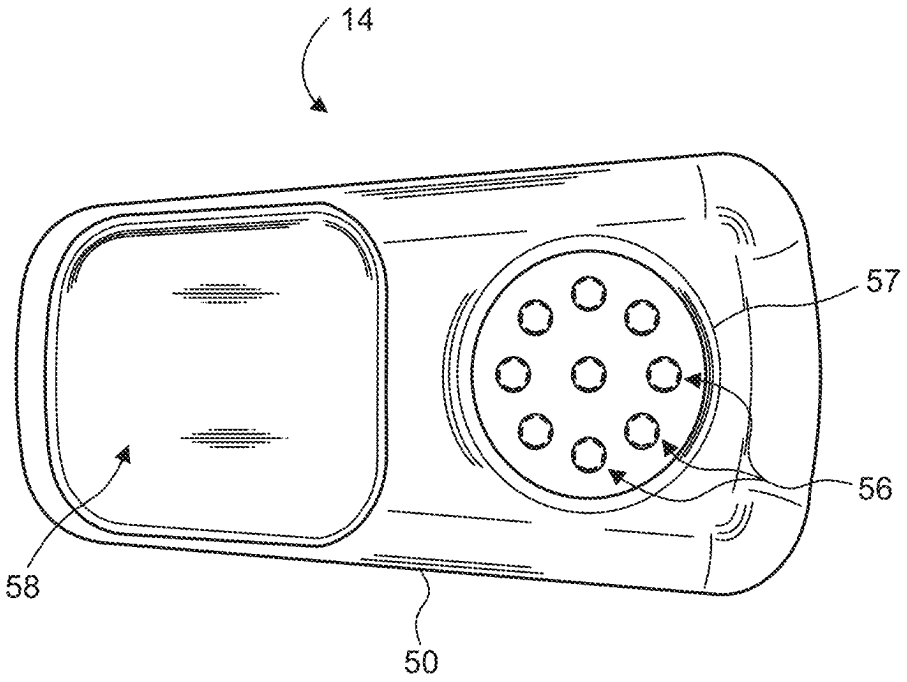


Fig. 8.

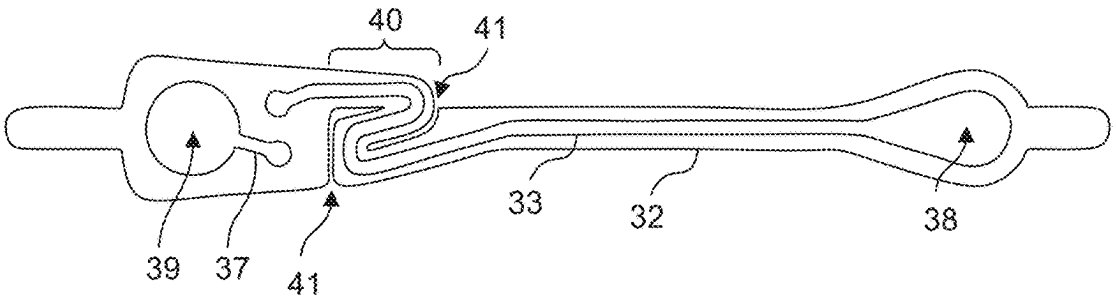


Fig. 9.

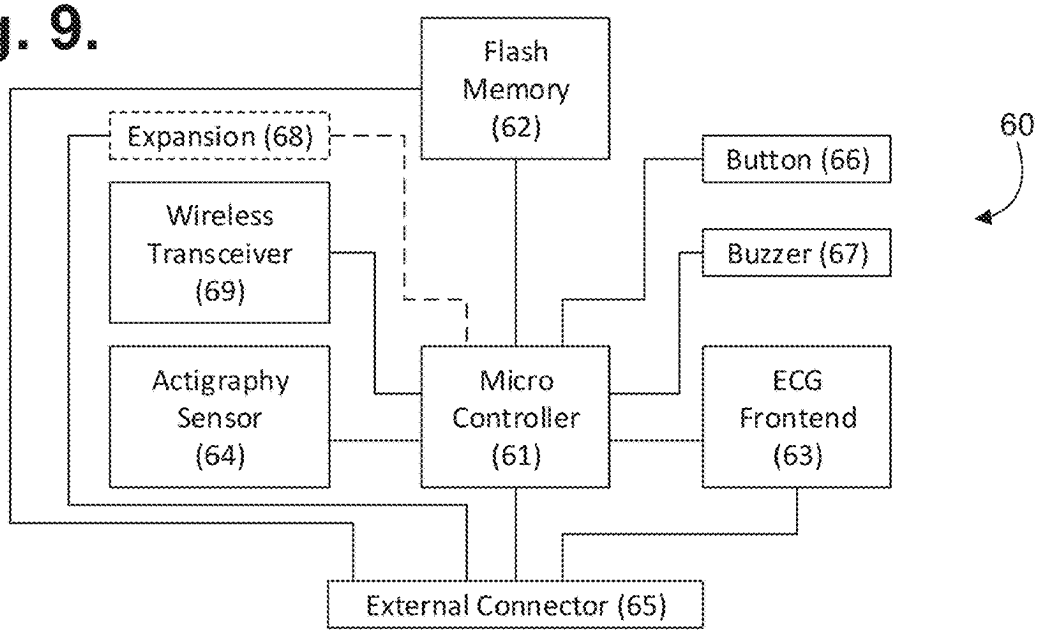


Fig. 10.

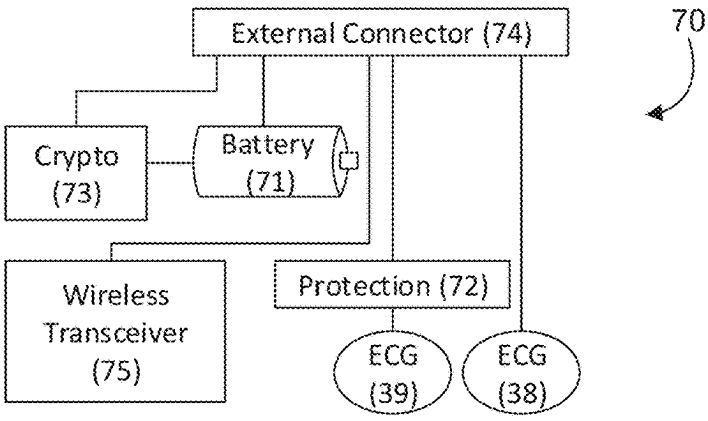


Fig. 11.

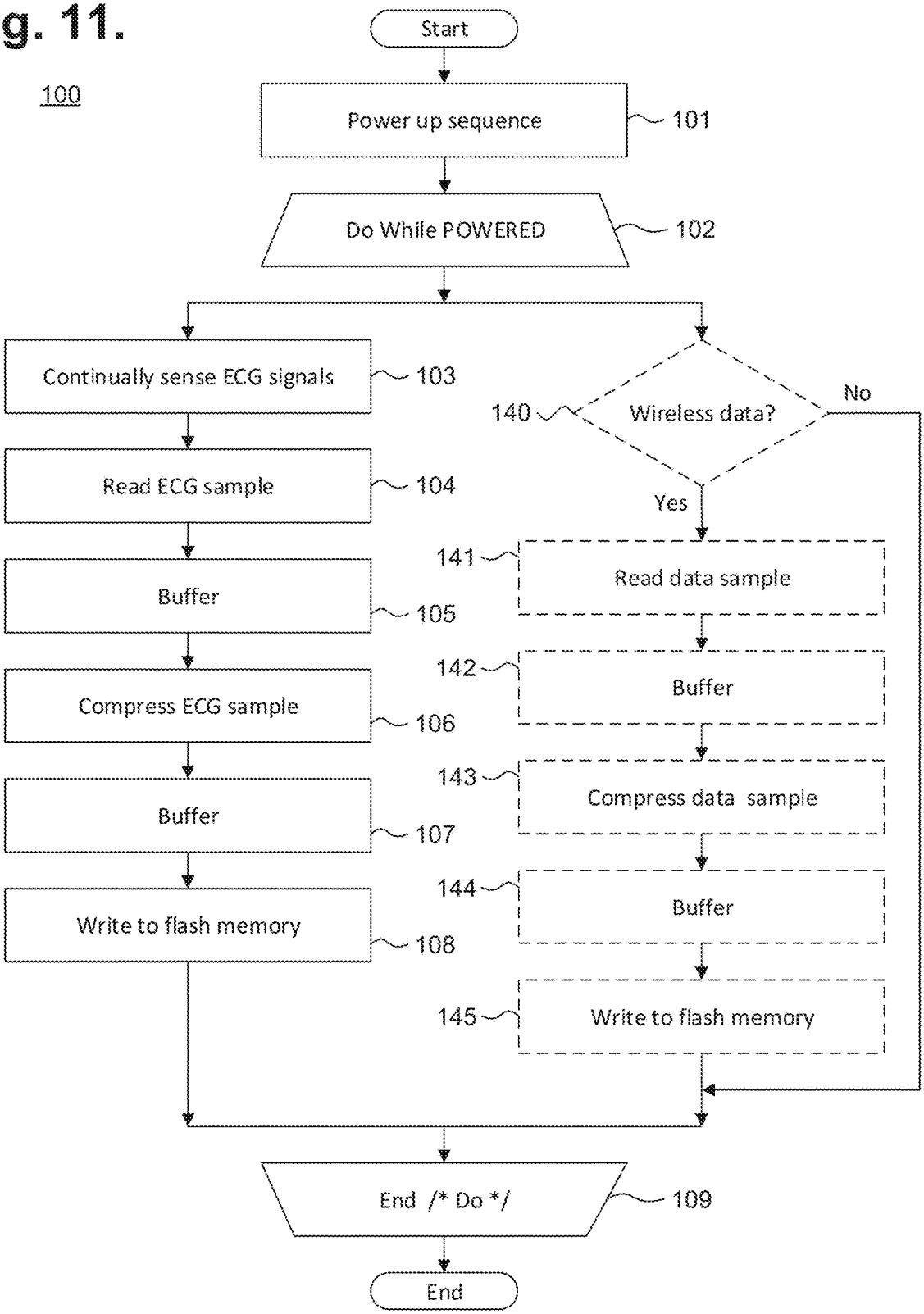

100
Start
Power up sequence
101
Do While POWERED
102
Continually sense ECG signals
103
Read ECG sample
104
Buffer
105
Compress ECG sample
106
Buffer
107
Write to flash memory
108
140
Wireless data?
No
Yes
141
Read data sample
142
Buffer
143
Compress data sample
144
Buffer
145
Write to flash memory
End /* Do */
109
End

Fig. 12.

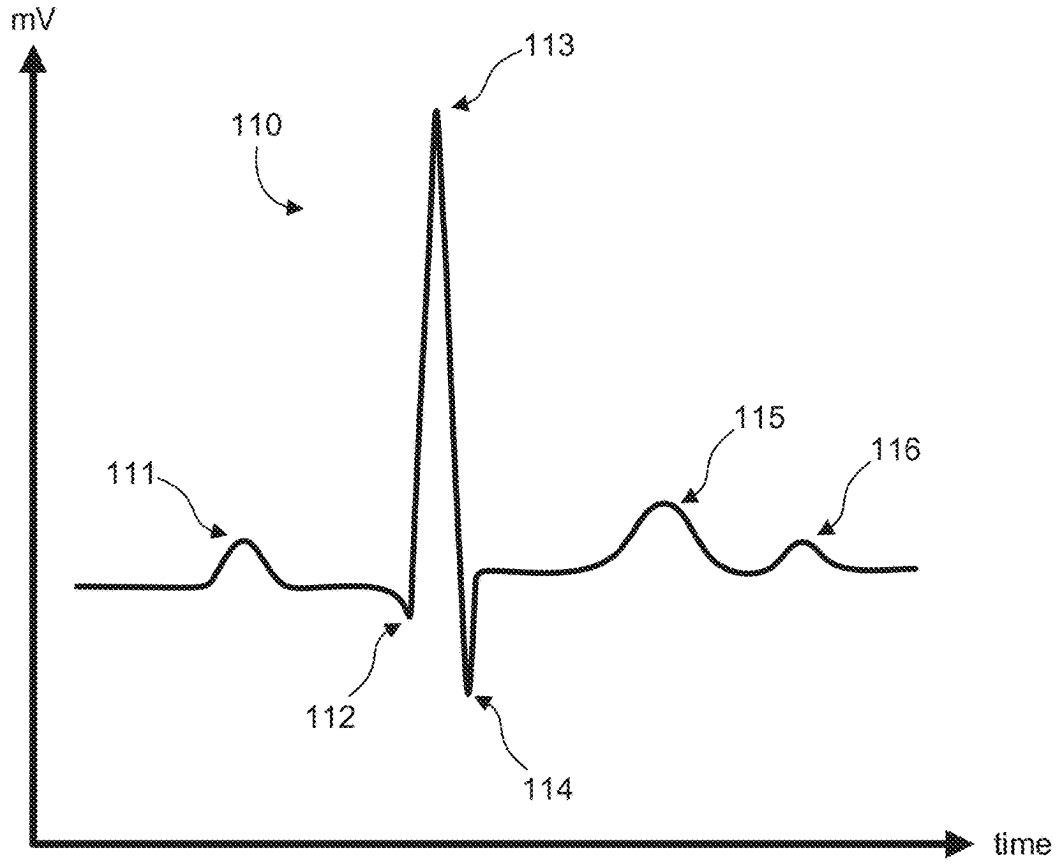
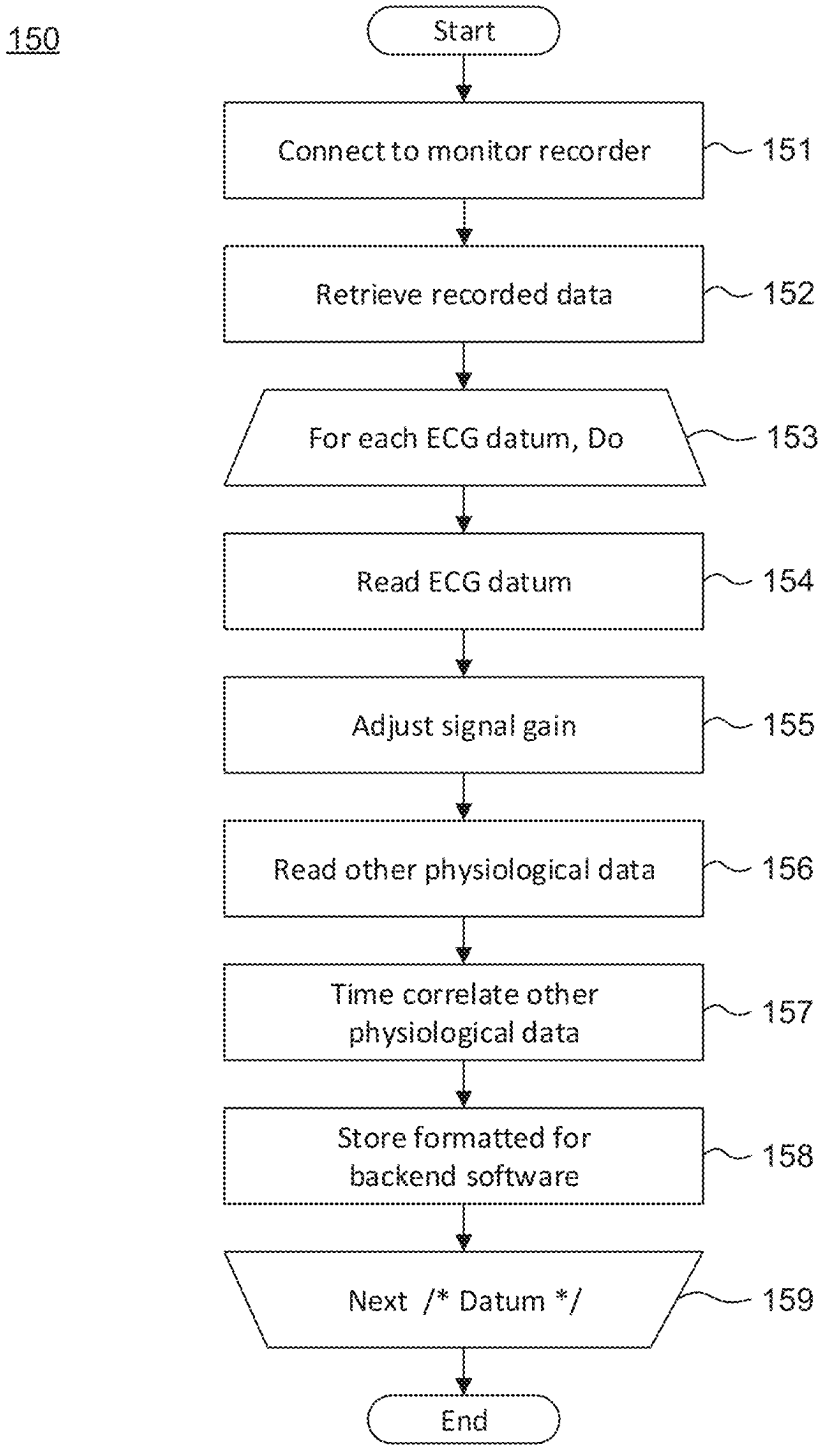


Fig. 13.


150
Start
Connect to monitor recorder
151
Retrieve recorded data
152
For each ECG datum, Do
153
Read ECG datum
154
Adjust signal gain
155
Read other physiological data
156
Time correlate other physiological data
157
Store formatted for backend software
158
Next /* Datum */
159
End

ELECTROCARDIOGRAMY PATCH

PRIORITY CLAIM AND CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 18/647,762, filed Apr. 26, 2024, titled ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 18/353,398, filed Jul. 17, 2023, titled ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 17/946,933, filed Sep. 16, 2022, titled ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 17/367,476, filed Jul. 5, 2021, titled ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 17/119,945, filed Dec. 11, 2020, titled ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 16/241,929, filed Jan. 7, 2019, titled REMOTE INTERFACING ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 15/818,437, filed Nov. 20, 2017, titled REMOTE INTERFACING ELECTROCARDIOGRAPHY PATCH, which is a continuation of U.S. patent application Ser. No. 15/256,266, filed Sep. 2, 2016, titled REMOTE INTERFACING OF EXTENDED WEAR ELECTROCARDIOGRAPHY AND PHYSIOLOGICAL SENSOR MONITOR, which is a continuation of U.S. patent application Ser. No. 14/082,071, filed Nov. 15, 2013, titled REMOTE INTERFACING OF EXTENDED WEAR ELECTROCARDIOGRAPHY AND PHYSIOLOGICAL SENSOR MONITOR, which is a continuation-in-part of U.S. patent application Ser. No. 14/080,717, filed Nov. 14, 2013, titled EXTENDED WEAR ELECTROCARDIOGRAPHY PATCH, which claims priority to U.S. Provisional Patent App. No. 61/882,403, filed Sep. 25, 2013, titled LONG-TERM WEARABLE PHYSIOLOGICAL MONITOR. U.S. patent application Ser. No. 14/082,071 is also a continuation-in-part of U.S. patent application Ser. No. 14/080,725, filed Nov. 14, 2013, titled EXTENDED WEAR AMBULATORY ELECTROCARDIOGRAPHY AND PHYSIOLOGICAL SENSOR MONITOR, which claims priority to U.S. Provisional Patent App. No. 61/882,403, filed Sep. 25, 2013, titled LONG-TERM WEARABLE PHYSIOLOGICAL MONITOR. The entire contents of these applications are incorporated by reference herein in their entirely and relied upon.

FIELD

This application relates in general to electrocardiographic monitoring and, in particular, to an electrocardiography patch.

BACKGROUND

The heart emits electrical signals as a by-product of the propagation of the action potentials that trigger depolarization of heart fibers. An electrocardiogram (ECG) measures and records such electrical potentials to visually depict the electrical activity of the heart over time. Conventionally, a standardized set format 12-lead configuration is used by an ECG machine to record cardiac electrical signals from well-established traditional chest locations. Electrodes at the end of each lead are placed on the skin over the anterior thoracic region of the patient's body to the lower right and to the lower left of the sternum, on the left anterior chest, and on the limbs. Sensed cardiac electrical activity is represented

by PQRSTU waveforms that can be interpreted post-ECG recordation to derive heart rate and physiology. The P-wave represents atrial electrical activity. The QRSTU components represent ventricular electrical activity.

An ECG is a tool used by physicians to diagnose heart problems and other potential health concerns. An ECG is a snapshot of heart function, typically recorded over 12 seconds, that can help diagnose rate and regularity of heartbeats, effect of drugs or cardiac devices, including pacemakers and implantable cardioverter-defibrillators (ICDs), and whether a patient has heart disease. ECGs are used in-clinic during appointments, and, as a result, are limited to recording only those heart-related aspects present at the time of recording. Sporadic conditions that may not show up during a spot ECG recording require other means to diagnose them. These disorders include fainting or syncope; rhythm disorders, such as tachyarrhythmias and bradyarrhythmias; apneic episodes; and other cardiac and related disorders. Thus, an ECG only provides a partial picture and can be insufficient for complete patient diagnosis of many cardiac disorders.

Diagnostic efficacy can be improved, when appropriate, through the use of long-term extended ECG monitoring. Recording sufficient ECG and related physiology over an extended period is challenging, and often essential to enabling a physician to identify events of potential concern. A 30-day observation period is considered the "gold standard" of ECG monitoring, yet achieving a 30-day observation day period has proven unworkable because such ECG monitoring systems are arduous to employ, cumbersome to the patient, and excessively costly. Ambulatory monitoring in-clinic is implausible and impracticable. Nevertheless, if a patient's ECG could be recorded in an ambulatory setting, thereby allowing the patient to engage in activities of daily living, the chances of acquiring meaningful information and capturing an abnormal event while the patient is engaged in normal activities becomes more likely to be achieved.

For instance, the long-term wear of ECG electrodes is complicated by skin irritation and the inability ECG electrodes to maintain continual skin contact after a day or two. Moreover, time, dirt, moisture, and other environmental contaminants, as well as perspiration, skin oil, and dead skin cells from the patient's body, can get between an ECG electrode, the non-conductive adhesive used to adhere the ECG electrode, and the skin's surface. All of these factors adversely affect electrode adhesion and the quality of cardiac signal recordings. Furthermore, the physical movements of the patient and their clothing impart various compressional, tensile, and torsional forces on the contact point of an ECG electrode, especially over long recording times, and an inflexibly fastened ECG electrode will be prone to becoming dislodged. Moreover, dislodgment may occur unbeknownst to the patient, making the ECG recordings worthless. Further, some patients may have skin that is susceptible to itching or irritation, and the wearing of ECG electrodes can aggravate such skin conditions. Thus, a patient may want or need to periodically remove or replace ECG electrodes during a long-term ECG monitoring period, whether to replace a dislodged electrode, reestablish better adhesion, alleviate itching or irritation, allow for cleansing of the skin, allow for showering and exercise, or for other purpose. Such replacement or slight alteration in electrode location actually facilitates the goal of recording the ECG signal for long periods of time.

Conventionally, Holter monitors are widely used for long-term extended ECG monitoring. Typically, they are used for only 24-48 hours. A typical Holter monitor is a wearable and

portable version of an ECG that include cables for each electrode placed on the skin and a separate battery-powered ECG recorder. The cable and electrode combination (or leads) are placed in the anterior thoracic region in a manner similar to what is done with an in-clinic standard ECG machine. The duration of a Holter monitoring recording depends on the sensing and storage capabilities of the monitor, as well as battery life. A "looping" Holter monitor (or event) can operate for a longer period of time by overwriting older ECG tracings, thence "recycling" storage in favor of extended operation, yet at the risk of losing event data. Although capable of extended ECG monitoring, Holter monitors are cumbersome, expensive and typically only available by medical prescription, which limits their usability. Further, the skill required to properly place the electrodes on the patient's chest hinders or precludes a patient from replacing or removing the precordial leads and usually involves moving the patient from the physician office to a specialized center within the hospital or clinic.

The ZIO XT Patch and ZIO Event Card devices, manufactured by iRhythm Tech., Inc., San Francisco, CA, are wearable stick-on monitoring devices that are typically worn on the upper left pectoral region to respectively provide continuous and looping ECG recording. The location is used to simulate surgically implanted monitors. Both of these devices are prescription-only and for single patient use. The ZIO XT Patch device is limited to a 14-day monitoring period, while the electrodes only of the ZIO Event Card device can be worn for up to 30 days. The ZIO XT Patch device combines both electronic recordation components, including battery, and physical electrodes into a unitary assembly that adheres to the patient's skin. The ZIO XT Patch device uses adhesive sufficiently strong to support the weight of both the monitor and the electrodes over an extended period of time and to resist disadherance from the patient's body, albeit at the cost of disallowing removal or relocation during the monitoring period. Moreover, throughout monitoring, the battery is continually depleted and battery capacity can potentially limit overall monitoring duration. The ZIO Event Card device is a form of downsized Holter monitor with a recorder component that must be removed temporarily during baths or other activities that could damage the non-waterproof electronics. Both devices represent compromises between length of wear and quality of ECG monitoring, especially with respect to ease of long term use, female-friendly fit, and quality of atrial (P-wave) signals.

In addition, with the advent of wireless communications and wearable computing, other types of personal ambulatory monitors, of varying degrees of sophistication, have become increasingly available. For example, adherents to the so-called "Quantified Self" movement combine wearable sensors and wearable computing to self-track activities of their daily lives, including inputs, states, and performance. The Nike+ FuelBand, manufactured by Nike Inc., Beaverton, OR, for instance, provides an activity tracker that is worn on the wrist and allows the wearer to temporally track the number of foot steps taken each day and an estimation of the calories burned. The activity tracker can interface with a smart phone device to allow a wearer to monitor their progress towards a fitness goal. Such quantified physiology, however, is typically tracked for only the personal use of the wearer and is not time-correlated to physician-supervised monitoring.

Therefore, a need remains for an extended wear continuously recording ECG monitor practicably capable of being worn for a long period of time in both men and women and capable of recording atrial signals reliably.

A further need remains for facilities to integrate wider-ranging physiological and "life tracking"-type data into long-term ECG and physiological data monitoring.

SUMMARY

Physiological monitoring can be provided through a wearable monitor that includes two components, a flexible extended wear electrode patch and a removable reusable monitor recorder. The wearable monitor sits centrally (in the midline) on the patient's chest along the sternum oriented top-to-bottom. The placement of the wearable monitor in a location at the sternal midline (or immediately to either side of the sternum), with its unique narrow "hourglass"-like shape, benefits long-term extended wear by removing the requirement that ECG electrodes be continually placed in the same spots on the skin throughout the monitoring period. Instead, the patient is free to place an electrode patch anywhere within the general region of the sternum, the area most likely to record high quality atrial signals or P-waves. The wearable monitor can also interoperate wirelessly with other wearable physiology and activity sensors and with wearable or mobile communications devices, including so-called "smart phones," to download monitoring data either in real-time or in batches. The monitor recorder can also be equipped with a wireless transceiver to either provide data or other information to, or receive data or other information from, an interfacing wearable physiology and activity sensor, or wearable or mobile communications devices for relay to a further device, such as a server, analysis, or other purpose.

One embodiment provides a remotely-interfaceable electrocardiography patch. The remotely-interfaceable electrocardiography patch includes a backing formed of a strip of material and an electrocardiographic electrode on each end of the backing to capture electrocardiographic signals. A flexible circuit includes a pair of circuit traces electrically coupled to the electrocardiographic electrodes. A wireless transceiver communicates at least one of the electrocardiographic signals and other physiological measures with one or more of a physiology and activity sensor, communication device, server, and personal computer.

A further embodiment provides an electrocardiography patch. The patch includes a backing and at least two electrocardiographic electrodes each positioned on the backing, across from another of the electrocardiographic electrodes, to capture electrocardiographic signals. A flexible circuit includes a pair of circuit traces electrically coupled to the electrocardiographic electrodes. A wireless transceiver communicates at least a portion of the electrocardiographic signals.

A still further embodiment provides an apparatus. A strip has first and second end sections, and a first surface and second surface. Two electrocardiographic electrodes are provided on the strip with one of the electrocardiographic electrodes provided on the first surface of the first end section of the strip and another of the electrocardiographic electrodes positioned on the first surface on the second end section of the strip. A flexible circuit is mounted to the second surface of the strip and includes a circuit trace electrically coupled to each of the electrocardiographic electrodes. A wireless transceiver is affixed on one of the first or second end sections, and a battery is positioned on one of

the first or second end sections. A processor is positioned on one of the first or second end sections and is housed separate from the battery.

The monitoring patch is especially suited to the female anatomy. The narrow longitudinal midsection can fit nicely within the intermammary cleft of the breasts without inducing discomfort, whereas conventional patch electrodes are wide and, if adhesed between the breasts, would cause chafing, irritation, frustration, and annoyance, leading to low patient compliance.

The foregoing aspects enhance ECG monitoring performance and quality, facilitating long-term ECG recording, critical to accurate arrhythmia diagnosis.

In addition, the foregoing aspects enhance comfort in women (and certain men), but not irritation of the breasts, by placing the monitoring patch in the best location possible for optimizing the recording of cardiac signals from the atrium, another feature critical to proper arrhythmia diagnosis.

Finally, the foregoing aspects as relevant to monitoring are equally applicable to recording other physiological measures, such as temperature, respiratory rate, blood sugar, oxygen saturation, and blood pressure, as well as other measures of body chemistry and physiology.

Still other embodiments will become readily apparent to those skilled in the art from the following detailed description, wherein are described embodiments by way of illustrating the best mode contemplated. As will be realized, other and different embodiments are possible and the embodiments' several details are capable of modifications in various obvious respects, all without departing from their spirit and the scope. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not as restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1** and **2** are diagrams showing, by way of examples, an extended wear electrocardiography and physiological sensor monitor respectively fitted to the sternal region of a female patient and a male patient.

FIG. **3** is a functional block diagram showing a system for remote interfacing of an extended wear electrocardiography and physiological sensor monitor in accordance with one embodiment.

FIG. **4** is a perspective view showing an extended wear electrode patch with a monitor recorder inserted.

FIG. **5** is a perspective view showing the monitor recorder of FIG. **4**.

FIG. **6** is a perspective view showing the extended wear electrode patch of FIG. **4** without a monitor recorder inserted.

FIG. **7** is a bottom plan view of the monitor recorder of FIG. **4**.

FIG. **8** is a top view showing the flexible circuit of the extended wear electrode patch of FIG. **4** when mounted above the flexible backing.

FIG. **9** is a functional block diagram showing the component architecture of the circuitry of the monitor recorder of FIG. **4**.

FIG. **10** is a functional block diagram showing the circuitry of the extended wear electrode patch of FIG. **4**.

FIG. **11** is a flow diagram showing a monitor recorder-implemented method for monitoring ECG data for use in the monitor recorder of FIG. **4**.

FIG. **12** is a graph showing, by way of example, a typical ECG waveform.

FIG. **13** is a flow diagram showing a method for offloading and converting ECG and other physiological data from an extended wear electrocardiography and physiological sensor monitor in accordance with one embodiment.

DETAILED DESCRIPTION

Physiological monitoring can be provided through a wearable monitor that includes two components, a flexible extended wear electrode patch and a removable reusable monitor recorder. FIGS. **1** and **2** are diagrams showing, by way of examples, an extended wear electrocardiography and physiological sensor monitor **12**, including a monitor recorder **14** in accordance with one embodiment, respectively fitted to the sternal region of a female patient **10** and a male patient **11**. The wearable monitor **12** sits centrally (in the midline) on the patient's chest along the sternum **13** oriented top-to-bottom with the monitor recorder **14** preferably situated towards the patient's head. In a further embodiment, the orientation of the wearable monitor **12** can be corrected post-monitoring, as further described infra. The electrode patch **15** is shaped to fit comfortably and conformal to the contours of the patient's chest approximately centered on the sternal midline **16** (or immediately to either side of the sternum **13**). The distal end of the electrode patch **15** extends towards the Xiphoid process and, depending upon the patient's build, may straddle the region over the Xiphoid process. The proximal end of the electrode patch **15**, located under the monitor recorder **14**, is below the manubrium and, depending upon patient's build, may straddle the region over the manubrium.

The placement of the wearable monitor **12** in a location at the sternal midline **16** (or immediately to either side of the sternum **13**) significantly improves the ability of the wearable monitor **12** to cutaneously sense cardiac electric signals, particularly the P-wave (or atrial activity) and, to a lesser extent, the QRS interval signals in the ECG waveforms that indicate ventricular activity, while simultaneously facilitating comfortable long-term wear for many weeks. The sternum **13** overlies the right atrium of the heart and the placement of the wearable monitor **12** in the region of the sternal midline **13** puts the ECG electrodes of the electrode patch **15** in a location better adapted to sensing and recording P-wave signals than other placement locations, say, the upper left pectoral region or lateral thoracic region or the limb leads. In addition, placing the lower or inferior pole (ECG electrode) of the electrode patch **15** over (or near) the Xiphoid process facilitates sensing of ventricular activity and provides superior recordation of the QRS interval.

When operated standalone, the monitor recorder **14** of the extended wear electrocardiography and physiological sensor monitor **12** senses and records the patient's ECG data into an onboard memory. In addition, the wearable monitor **12** can interoperate with other devices. FIG. **3** is a functional block diagram showing a system **120** for remote interfacing of an extended wear electrocardiography and physiological sensor monitor **12** in accordance with one embodiment. The monitor recorder **14** is a reusable component that can be fitted during patient monitoring into a non-conductive receptacle provided on the electrode patch **15**, as further described infra with reference to FIG. **4**, and later removed for offloading of stored ECG data or to receive revised programming. The monitor recorder **14** can then be connected to a download station **125**, which could be a programmer or other device that permits the retrieval of stored ECG monitoring data, execution of diagnostics on or programming of the monitor recorder **14**, or performance of other functions. The monitor

recorder **14** has a set of electrical contacts (not shown) that enable the monitor recorder **14** to physically interface to a set of terminals **128** on a paired receptacle **127** of the download station **125**. In turn, the download station **125** executes a communications or offload program **126** ("Offload") or similar program that interacts with the monitor recorder **14** via the physical interface to retrieve the stored ECG monitoring data. The download station **125** could be a server, personal computer, tablet or handheld computer, smart mobile device, or purpose-built programmer designed specific to the task of interfacing with a monitor recorder **14**. Still other forms of download station **125** are possible.

Upon retrieving stored ECG monitoring data from a monitor recorder **14**, middleware first operates on the retrieved data to adjust the ECG capture quality, as necessary, and to convert the retrieved data into a format suitable for use by third party post-monitoring analysis software, as further described infra with reference to FIG. **13**. The formatted data can then be retrieved from the download station **125** over a hard link **135** using a control program **137** ("Ctl") or analogous application executing on a personal computer **136** or other connectable computing device, via a communications link (not shown), whether wired or wireless, or by physical transfer of storage media (not shown). The personal computer **136** or other connectable device may also execute middleware that converts ECG data and other information into a format suitable for use by a third-party post-monitoring analysis program, as further described infra with reference to FIG. **13**. Note that formatted data stored on the personal computer **136** would have to be maintained and safeguarded in the same manner as electronic medical records (EMRs) **134** in the secure database **124**, as further discussed infra. In a further embodiment, the download station **125** is able to directly interface with other devices over a computer communications network **121**, which could be some combination of a local area network and a wide area network, including the Internet, over a wired or wireless connection.

A client-server model could be used to employ a server **122** to remotely interface with the download station **125** over the network **121** and retrieve the formatted data or other information. The server **122** executes a patient management program **123** ("Mgt") or similar application that stores the retrieved formatted data and other information in a secure database **124** cataloged in that patient's EMRs **134**. In addition, the patient management program **123** could manage a subscription service that authorizes a monitor recorder **14** to operate for a set period of time or under pre-defined operational parameters.

The patient management program **123**, or other trusted application, also maintains and safeguards the secure database **124** to limit access to patient EMRs **134** to only authorized parties for appropriate medical or other uses, such as mandated by state or federal law, such as under the Health Insurance Portability and Accountability Act (HIPAA) or per the European Union's Data Protection Directive. For example, a physician may seek to review and evaluate his patient's ECG monitoring data, as securely stored in the secure database **124**. The physician would execute an application program **130** ("Pgm"), such as a post-monitoring ECG analysis program, on a personal computer **129** or other connectable computing device, and, through the application **130**, coordinate access to his patient's EMRs **134** with the patient management program **123**. Other schemes and safeguards to protect and maintain the integrity of patient EMRs **134** are possible.

The wearable monitor **12** can interoperate wirelessly with other wearable physiology and activity sensors **131** and with wearable or mobile communications devices **133**. Wearable physiology and activity sensors **131** encompass a wide range of wirelessly interconnectable devices that measure or monitor data physical to the patient's body, such as heart rate, temperature, blood pressure, and so forth; physical states, such as movement, sleep, footsteps, and the like; and performance, including calories burned or estimated blood glucose level. These devices originate both within the medical community to sense and record traditional medical physiology that could be useful to a physician in arriving at a patient diagnosis or clinical trajectory, as well as from outside the medical community, from, for instance, sports or lifestyle product companies who seek to educate and assist individuals with self-quantifying interests.

Frequently, wearable physiology and activity sensors **131** are capable of wireless interfacing with wearable or mobile communications devices **133**, particularly smart mobile devices, including so-called "smart phones," to download monitoring data either in real-time or in batches. The wearable or mobile communications device **133** executes an application ("App") that can retrieve the data collected by the wearable physiology and activity sensor **131** and evaluate the data to generate information of interest to the wearer, such as an estimation of the effectiveness of the wearer's exercise efforts. Still other wearable or mobile communications device **133** functions on the collected data are possible.

The wearable or mobile communications devices **133** could also serve as a conduit for providing the data collected by the wearable physiology and activity sensor **131** to a server **122**, or, similarly, the wearable physiology and activity sensor **131** could itself directly provide the collected data to the server **122**. The server **122** could then merge the collected data into the wearer's EMRs **134** in the secure database **124**, if appropriate (and permissible), or the server **122** could perform an analysis of the collected data, perhaps based by comparison to a population of like wearers of the wearable physiology and activity sensor **131**. Still other server **122** functions on the collected data are possible.

Finally, the monitor recorder **14** can also be equipped with a wireless transceiver, as further described infra with reference to FIGS. **9** and **10**. Thus, when wireless-enabled, both wearable physiology and activity sensors **131** and wearable or mobile communications devices **133** could wirelessly interface with the monitor recorder **14**, which could either provide data or other information to, or receive data or other information from an interfacing device for relay to a further device, such as the server **122**, analysis, or other purpose. In addition, the monitor recorder **14** could wirelessly interface directly with the server **122**, personal computer **129**, or other computing device connectable over the network **121**, when the monitor recorder **14** is appropriately equipped for interfacing with such devices. Still other types of remote interfacing of the monitor recorder **14** are possible.

During use, the electrode patch **15** is first adhesed to the skin along the sternal midline **16** (or immediately to either side of the sternum **13**). A monitor recorder **14** is then snapped into place on the electrode patch **15** to initiate ECG monitoring. FIG. **4** is a perspective view showing an extended wear electrode patch **15** with a monitor recorder **14** in accordance with one embodiment inserted. The body of the electrode patch **15** is preferably constructed using a flexible backing **20** formed as an elongated strip **21** of wrap knit or similar stretchable material with a narrow longitudinal mid-section **23** evenly tapering inward from both sides. A pair of cut-outs **22** between the distal and proximal

ends of the electrode patch **15** create a narrow longitudinal midsection **23** or "isthmus" and defines an elongated "hourglass"-like shape, when viewed from above.

The electrode patch **15** incorporates features that significantly improve wearability, performance, and patient comfort throughout an extended monitoring period. During wear, the electrode patch **15** is susceptible to pushing, pulling, and torqueing movements, including compressional and torsional forces when the patient bends forward, and tensile and torsional forces when the patient leans backwards. To counter these stress forces, the electrode patch **15** incorporates strain and crimp reliefs, such as described in commonly-assigned U.S. Patent, entitled "Extended Wear Electrocardiography Patch," U.S. Pat. No. 9,545,204, issued Jan. 17, 2017, the disclosure of which is incorporated by reference. In addition, the cut-outs **22** and longitudinal midsection **23** help minimize interference with and discomfort to breast tissue, particularly in women (and gynecomastic men). The cut-outs **22** and longitudinal midsection **23** further allow better conformity of the electrode patch **15** to sternal bowing and to the narrow isthmus of flat skin that can occur along the bottom of the intermammary cleft between the breasts, especially in buxom women. The cut-outs **22** and longitudinal midsection **23** help the electrode patch **15** fit nicely between a pair of female breasts in the intermammary cleft. Still other shapes, cut-outs and conformities to the electrode patch **15** are possible.

The monitor recorder **14** removably and reusably snaps into an electrically non-conductive receptacle **25** during use. The monitor recorder **14** contains electronic circuitry for recording and storing the patient's electrocardiography as sensed via a pair of ECG electrodes provided on the electrode patch **15**, such as described in commonly-assigned U.S. Patent, entitled "Extended Wear Ambulatory Electrocardiography and Physiological Sensor Monitor," U.S. Pat. No. 9,730,593, issued Aug. 15, 2017, the disclosure which is incorporated by reference. The non-conductive receptacle **25** is provided on the top surface of the flexible backing **20** with a retention catch **26** and tension clip **27** molded into the non-conductive receptacle **25** to conformably receive and securely hold the monitor recorder **14** in place.

The monitor recorder **14** includes a sealed housing that snaps into place in the non-conductive receptacle **25**. FIG. **5** is a perspective view showing the monitor recorder **14** of FIG. **4**. The sealed housing **50** of the monitor recorder **14** intentionally has a rounded isosceles trapezoidal-like shape **52**, when viewed from above, such as described in commonly-assigned U.S. Design Patent, entitled "Electrocardiography Monitor," No. D717,955, issued Nov. 18, 2014, the disclosure of which is incorporated by reference. The edges **51** along the top and bottom surfaces are rounded for patient comfort. The sealed housing **50** is approximately 47 mm long, 23 mm wide at the widest point, and 7 mm high, excluding a patient-operable tactile-feedback button **55**. The sealed housing **50** can be molded out of polycarbonate, ABS, or an alloy of those two materials. The button **55** is waterproof and the button's top outer surface is molded silicon rubber or similar soft pliable material. A retention detent **53** and tension detent **54** are molded along the edges of the top surface of the housing **50** to respectively engage the retention catch **26** and the tension clip **27** molded into non-conductive receptacle **25**. Other shapes, features, and conformities of the sealed housing **50** are possible.

The electrode patch **15** is intended to be disposable. The monitor recorder **14**, however, is reusable and can be transferred to successive electrode patches **15** to ensure continuity of monitoring. The placement of the wearable monitor **12** in a location at the sternal midline **16** (or immediately to either side of the sternum **13**) benefits long-term extended wear by removing the requirement that ECG electrodes be continually placed in the same spots on the skin throughout the monitoring period. Instead, the patient is free to place an electrode patch **15** anywhere within the general region of the sternum **13**.

As a result, at any point during ECG monitoring, the patient's skin is able to recover from the wearing of an electrode patch **15**, which increases patient comfort and satisfaction, while the monitor recorder **14** ensures ECG monitoring continuity with minimal effort. A monitor recorder **14** is merely unsnapped from a worn out electrode patch **15**, the worn out electrode patch **15** is removed from the skin, a new electrode patch **15** is adhered to the skin, possibly in a new spot immediately adjacent to the earlier location, and the same monitor recorder **14** is snapped into the new electrode patch **15** to reinitiate and continue the ECG monitoring.

During use, the electrode patch **15** is first adhered to the skin in the sternal region. FIG. **6** is a perspective view showing the extended wear electrode patch **15** of FIG. **4** without a monitor recorder **14** inserted. A flexible circuit **32** is adhered to each end of the flexible backing **20**. A distal circuit trace **33** and a proximal circuit trace (not shown) electrically couple ECG electrodes (not shown) to a pair of electrical pads **34**. The electrical pads **34** are provided within a moisture-resistant seal **35** formed on the bottom surface of the non-conductive receptacle **25**. When the monitor recorder **14** is securely received into the non-conductive receptacle **25**, that is, snapped into place, the electrical pads **34** interface to electrical contacts (not shown) protruding from the bottom surface of the monitor recorder **14**, and the moisture-resistant seal **35** enables the monitor recorder **14** to be worn at all times, even during bathing or other activities that could expose the monitor recorder **14** to moisture.

In addition, a battery compartment **36** is formed on the bottom surface of the non-conductive receptacle **25**, and a pair of battery leads (not shown) electrically interface the battery to another pair of the electrical pads **34**. The battery contained within the battery compartment **35** can be replaceable, rechargeable or disposable.

The monitor recorder **14** draws power externally from the battery provided in the non-conductive receptacle **25**, thereby uniquely obviating the need for the monitor recorder **14** to carry a dedicated power source. FIG. **7** is a bottom plan view of the monitor recorder **14** of FIG. **4**. A cavity **58** is formed on the bottom surface of the sealed housing **50** to accommodate the upward projection of the battery compartment **36** from the bottom surface of the non-conductive receptacle **25**, when the monitor recorder **14** is secured in place on the non-conductive receptacle **25**. A set of electrical contacts **56** protrude from the bottom surface of the sealed housing **50** and are arranged in alignment with the electrical pads **34** provided on the bottom surface of the non-conductive receptacle **25** to establish electrical connections between the electrode patch **15** and the monitor recorder **14**. In addition, a seal coupling **57** circumferentially surrounds the set of electrical contacts **56** and securely mates with the moisture-resistant seal **35** formed on the bottom surface of the non-conductive receptacle **25**.

The placement of the flexible backing **20** on the sternal midline **16** (or immediately to either side of the sternum **13**) also helps to minimize the side-to-side movement of the wearable monitor **12** in the left- and right-handed directions during wear. To counter the dislodgment of the flexible backing **20** due to compressional and torsional forces, a

layer of non-irritating adhesive, such as hydrocolloid, is provided at least partially on the underside, or contact, surface of the flexible backing **20**, but only on the distal end **30** and the proximal end **31**. As a result, the underside, or contact surface of the longitudinal midsection **23** does not have an adhesive layer and remains free to move relative to the skin. Thus, the longitudinal midsection **23** forms a crimp relief that respectively facilitates compression and twisting of the flexible backing **20** in response to compressional and torsional forces. Other forms of flexible backing crimp reliefs are possible.

Unlike the flexible backing **20**, the flexible circuit **32** is only able to bend and cannot stretch in a planar direction. The flexible circuit **32** can be provided either above or below the flexible backing **20**. FIG. **8** is a top view showing the flexible circuit **32** of the extended wear electrode patch **15** of FIG. **4** when mounted above the flexible backing **20**. A distal ECG electrode **38** and proximal ECG electrode **39** are respectively coupled to the distal and proximal ends of the flexible circuit **32**. A strain relief **40** is defined in the flexible circuit **32** at a location that is partially underneath the battery compartment **36** when the flexible circuit **32** is affixed to the flexible backing **20**. The strain relief **40** is laterally extendable to counter dislodgment of the ECG electrodes **38**, **39** due to tensile and torsional forces. A pair of strain relief cutouts **41** partially extend transversely from each opposite side of the flexible circuit **32** and continue longitudinally towards each other to define in 'S'-shaped pattern, when viewed from above. The strain relief respectively facilitates longitudinal extension and twisting of the flexible circuit **32** in response to tensile and torsional forces. Other forms of circuit board strain relief are possible.

ECG monitoring and other functions performed by the monitor recorder **14** are provided through a micro controlled architecture. FIG. **9** is a functional block diagram showing the component architecture of the circuitry **60** of the monitor recorder **14** of FIG. **4**. The circuitry **60** is externally powered through a battery provided in the non-conductive receptacle **25** (shown in FIG. **6**). Both power and raw ECG signals, which originate in the pair of ECG electrodes **38**, **39** (shown in FIG. **8**) on the distal and proximal ends of the electrode patch **15**, are received through an external connector **65** that mates with a corresponding physical connector on the electrode patch **15**. The external connector **65** includes the set of electrical contacts **56** that protrude from the bottom surface of the sealed housing **50** and which physically and electrically interface with the set of pads **34** provided on the bottom surface of the non-conductive receptacle **25**. The external connector includes electrical contacts **56** for data download, microcontroller communications, power, analog inputs, and a peripheral expansion port. The arrangement of the pins on the electrical connector **65** of the monitor recorder **14** and the device into which the monitor recorder **14** is attached, whether an electrode patch **15** or download station (not shown), follow the same electrical pin assignment convention to facilitate interoperability. The external connector **65** also serves as a physical interface to a download station that permits the retrieval of stored ECG monitoring data, communication with the monitor recorder **14**, and performance of other functions.

Operation of the circuitry **60** of the monitor recorder **14** is managed by a microcontroller **61**. The micro-controller **61** includes a program memory unit containing internal flash memory that is readable and writeable. The internal flash memory can also be programmed externally. The microcontroller **61** draws power externally from the battery provided on the electrode patch **15** via a pair of the electrical contacts **56**. The microcontroller **61** connects to the ECG front end circuit **63** that measures raw cutaneous electrical signals and generates an analog ECG signal representative of the electrical activity of the patient's heart over time.

The circuitry **60** of the monitor recorder **14** also includes a flash memory **62**, which the micro-controller **61** uses for storing ECG monitoring data and other physiology and information. The flash memory **62** also draws power externally from the battery provided on the electrode patch **15** via a pair of the electrical contacts **56**. Data is stored in a serial flash memory circuit, which supports read, erase and program operations over a communications bus. The flash memory **62** enables the microcontroller **61** to store digitized ECG data. The communications bus further enables the flash memory **62** to be directly accessed externally over the external connector **65** when the monitor recorder **14** is interfaced to a download station.

The circuitry **60** of the monitor recorder **14** further includes an actigraphy sensor **64** implemented as a 3-axis accelerometer. The accelerometer may be configured to generate interrupt signals to the microcontroller **61** by independent initial wake up and free fall events, as well as by device position. In addition, the actigraphy provided by the accelerometer can be used during post-monitoring analysis to correct the orientation of the monitor recorder **14** if, for instance, the monitor recorder **14** has been inadvertently installed upside down, that is, with the monitor recorder **14** oriented on the electrode patch **15** towards the patient's feet, as well as for other event occurrence analyses, such as described in commonly-assigned U.S. Pat. No. 9,737,224, issued Aug. 22, 2017, the disclosure of which is incorporated by reference.

The circuitry **60** of the monitor recorder **14** includes a wireless transceiver **69** that can provides wireless interfacing capabilities. The wireless transceiver **69** also draws power externally from the battery provided on the electrode patch **15** via a pair of the electrical contacts **56**. The wireless transceiver **69** can be implemented using one or more forms of wireless communications, including the IEEE 802.11 computer communications standard, that is Wi-Fi; the 4G mobile phone mobile communications standard; the Bluetooth data exchange standard; or other wireless communications or data exchange standards and protocols. The type of wireless interfacing capability could limit the range of interoperability of the monitor recorder **14**; for instance, Bluetooth-based implementations are designed for low power consumption with a short communications range.

The microcontroller **61** includes an expansion port that also utilizes the communications bus. External devices, separately drawing power externally from the battery provided on the electrode patch **15** or other source, can interface to the microcontroller **61** over the expansion port in half duplex mode. For instance, an external physiology sensor can be provided as part of the circuitry **60** of the monitor recorder **14**, or can be provided on the electrode patch **15** with communication with the micro-controller **61** provided over one of the electrical contacts **56**. The physiology sensor can include an SpO_2 sensor, blood pressure sensor, temperature sensor, respiratory rate sensor, glucose sensor, airflow sensor, volumetric pressure sensing, or other types of sensor or telemetric input sources. For instance, the integration of an airflow sensor is described in commonly-assigned U.S. Pat. No. 9,364,155, issued Jun. 14, 2016, the disclosure which is incorporated by reference.

Finally, the circuitry **60** of the monitor recorder **14** includes patient-interfaceable components, including a tactile feedback button **66**, which a patient can press to mark

events or to perform other functions, and a buzzer **67**, such as a speaker, magnetic resonator or piezoelectric buzzer. The buzzer **67** can be used by the microcontroller **61** to output feedback to a patient such as to confirm power up and initiation of ECG monitoring. Still other components as part of the circuitry **60** of the monitor recorder **14** are possible.

While the monitor recorder **14** operates under micro control, most of the electrical components of the electrode patch **15** operate passively. FIG. **10** is a functional block diagram showing the circuitry **70** of the extended wear electrode patch **15** of FIG. **4**. The circuitry **70** of the electrode patch **15** is electrically coupled with the circuitry **60** of the monitor recorder **14** through an external connector **74**. The external connector **74** is terminated through the set of pads **34** provided on the bottom of the non-conductive receptacle **25**, which electrically mate to corresponding electrical contacts **56** protruding from the bottom surface of the sealed housing **50** to electrically interface the monitor recorder **14** to the electrode patch **15**.

The circuitry **70** of the electrode patch **15** performs three primary functions. First, a battery **71** is provided in a battery compartment formed on the bottom surface of the non-conductive receptacle **25**. The battery **71** is electrically interfaced to the circuitry **60** of the monitor recorder **14** as a source of external power. The unique provisioning of the battery **71** on the electrode patch **15** provides several advantages. First, the locating of the battery **71** physically on the electrode patch **15** lowers the center of gravity of the overall wearable monitor **12** and thereby helps to minimize shear forces and the effects of movements of the patient and clothing. Moreover, the housing **50** of the monitor recorder **14** is sealed against moisture and providing power externally avoids having to either periodically open the housing **50** for the battery replacement, which also creates the potential for moisture intrusion and human error, or to recharge the battery, which can potentially take the monitor recorder **14** off line for hours at a time. In addition, the electrode patch **15** is intended to be disposable, while the monitor recorder **14** is a reusable component. Each time that the electrode patch **15** is replaced, a fresh battery is provided for the use of the monitor recorder **14**, which enhances ECG monitoring performance quality and duration of use. Finally, the architecture of the monitor recorder **14** is open, in that other physiology sensors or components can be added by virtue of the expansion port of the microcontroller **61**. Requiring those additional sensors or components to draw power from a source external to the monitor recorder **14** keeps power considerations independent of the monitor recorder **14**. Thus, a battery of higher capacity could be introduced when needed to support the additional sensors or components without effecting the monitor recorders circuitry **60**.

Second, the pair of ECG electrodes **38**, **39** respectively provided on the distal and proximal ends of the flexible circuit **32** are electrically coupled to the set of pads **34** provided on the bottom of the non-conductive receptacle **25** by way of their respective circuit traces **33**, **37**. The signal ECG electrode **39** includes a protection circuit **72**, which is an inline resistor that protects the patient from excessive leakage current.

Last, in a further embodiment, the circuitry **70** of the electrode patch **15** includes a cryptographic circuit **73** to authenticate an electrode patch **15** for use with a monitor recorder **14**. The cryptographic circuit **73** includes a device capable of secure authentication and validation. The cryptographic device **73** ensures that only genuine, non-expired, safe, and authenticated electrode patches **15** are permitted to provide monitoring data to a monitor recorder **14**, such as described in commonly-assigned U.S. Pat. No. 9,655,538, issued May 23, 2017, the disclosure which is incorporated by reference.

In a further embodiment, the circuitry **70** of the electrode patch **15** includes a wireless transceiver **75**, in lieu the including of the wireless transceiver **69** in the circuitry **60** of the monitor recorder **14**, which interfaces with the microcontroller **61** over the microcontroller's expansion port via the external connector **74**.

The monitor recorder **14** continuously monitors the patient's heart rate and physiology. FIG. **11** is a flow diagram showing a monitor recorder-implemented method **100** for monitoring ECG data for use in the monitor recorder **14** of FIG. **4**. Initially, upon being connected to the set of pads **34** provided with the non-conductive receptacle **25** when the monitor recorder **14** is snapped into place, the microcontroller **61** executes a power up sequence (step **101**). During the power up sequence, the voltage of the battery **71** is checked, the state of the flash memory **62** is confirmed, both in terms of operability check and available capacity, and microcontroller operation is diagnostically confirmed. In a further embodiment, an authentication procedure between the microcontroller **61** and the electrode patch **15** are also performed.

Following satisfactory completion of the power up sequence, an iterative processing loop (steps **102**-**109**) is continually executed by the microcontroller **61**. During each iteration (step **102**) of the processing loop, the ECG frontend **63** (shown in FIG. **9**) continually senses the cutaneous ECG electrical signals (step **103**) via the ECG electrodes **38**, **29** and is optimized to maintain the integrity of the P-wave. A sample of the ECG signal is read (step **104**) by the microcontroller **61** by sampling the analog ECG signal output front end **63**. FIG. **12** is a graph showing, by way of example, a typical ECG waveform **110**. The x-axis represents time in approximate units of tenths of a second. The y-axis represents cutaneous electrical signal strength in approximate units of millivolts. The P-wave **111** has a smooth, normally upward, that is, positive, waveform that indicates atrial depolarization. The QRS complex usually begins with the downward deflection of a Q wave **112**, followed by a larger upward deflection of an R-wave **113**, and terminated with a downward waveform of the S wave **114**, collectively representative of ventricular depolarization. The T wave **115** is normally a modest upward waveform, representative of ventricular depolarization, while the U wave **116**, often not directly observable, indicates the recovery period of the Purkinje conduction fibers.

Sampling of the R-to-R interval enables heart rate information derivation. For instance, the R-to-R interval represents the ventricular rate and rhythm, while the P-to-P interval represents the atrial rate and rhythm. Importantly, the PR interval is indicative of atrioventricular (AV) conduction time and abnormalities in the PR interval can reveal underlying heart disorders, thus representing another reason why the P-wave quality achievable by the extended wear ambulatory electrocardiography and physiological sensor monitor described herein is medically unique and important. The long-term observation of these ECG indicia, as provided through extended wear of the wearable monitor **12**, provides valuable insights to the patient's cardiac function and overall well-being.

Each sampled ECG signal, in quantized and digitized form, is temporarily staged in buffer (step **105**), pending compression preparatory to storage in the flash memory **62** (step **106**). Following compression, the compressed ECG digitized sample is again buffered (step **107**), then written to

the flash memory **62** (step **108**) using the communications bus. Processing continues (step **109**), so long as the monitoring recorder **14** remains connected to the electrode patch **15** (and storage space remains available in the flash memory **62**), after which the processing loop is exited and execution terminates. Still other operations and steps are possible.

In a further embodiment, the monitor recorder **14** also continuously receives data from wearable physiology and activity sensors **131** and wearable or mobile communications devices **133** (shown in FIG. **3**). The data is received in a conceptually-separate execution thread as part of the iterative processing loop (steps **102-109**) continually executed by the microcontroller **61**. During each iteration (step **102**) of the processing loop, if wireless data is available (step **140**), a sample of the wireless is read (step **141**) by the microcontroller **61** and, if necessary, converted into a digital signal by the onboard ADC of the microcontroller **61**. Each wireless data sample, in quantized and digitized form, is temporarily staged in buffer (step **142**), pending compression preparatory to storage in the flash memory **62** (step **143**). Following compression, the compressed wireless data sample is again buffered (step **144**), then written to the flash memory **62** (step **145**) using the communications bus. Processing continues (step **109**), so long as the monitoring recorder **14** remains connected to the electrode patch **15** (and storage space remains available in the flash memory **62**), after which the processing loop is exited and execution terminates. Still other operations and steps are possible.

The monitor recorder **14** stores ECG data and other information in the flash memory **62** (shown in FIG. **9**) using a proprietary format that includes data compression. As a result, data retrieved from a monitor recorder **14** must first be converted into a format suitable for use by third party post-monitoring analysis software. FIG. **13** is a flow diagram showing a method **150** for offloading and converting ECG and other physiological data from an extended wear electrocardiography and physiological sensor monitor **12** in accordance with one embodiment. The method **150** can be implemented in software and execution of the software can be performed on a download station **125**, which could be a programmer or other device, or a computer system, including a server **122** or personal computer **129**, such as further described supra with reference to FIG. **3**, as a series of process or method modules or steps. For convenience, the method **150** will be described in the context of being performed by a personal computer **136** or other connectable computing device (shown in FIG. **3**) as middleware that converts ECG data and other information into a format suitable for use by a third-party post-monitoring analysis program. Execution of the method **150** by a computer system would be analogous mutatis mutandis.

Initially, the download station **125** is connected to the monitor recorder **14** (step **151**), such as by physically interfacing to a set of terminals **128** on a paired receptacle **127** or by wireless connection, if available. The data stored on the monitor recorder **14**, including ECG and physiological monitoring data, other recorded data, and other information are retrieved (step **152**) over a hard link **135** using a control program **137** ("Ctl") or analogous application executing on a personal computer **136** or other connectable computing device.

The data retrieved from the monitor recorder **14** is in a proprietary storage format and each datum of recorded ECG monitoring data, as well as any other physiological data or other information, must be converted, so that the data can be used by a third-party post-monitoring analysis program. Each datum of ECG monitoring data is converted by the middleware (steps **153-159**) in an iterative processing loop. During each iteration (step **153**), the ECG datum is read (step **154**) and, if necessary, the gain of the ECG signal is adjusted (step **155**) to compensate, for instance, for relocation or replacement of the electrode patch **15** during the monitoring period.

In addition, depending upon the configuration of the wearable monitor **12**, other physiological data (or other information), including patient events, such as a fall, peak activity level, sleep detection, Detection of patient activity levels and states, and so on, may be recorded along with the ECG monitoring data. For instance, actigraphy data may have been sampled by the actigraphy sensor **64** based on a sensed event occurrence, such as a sudden change in orientation due to the patient taking a fall. In response, the monitor recorder **14** will embed the actigraphy data samples into the stream of data, including ECG monitoring data, that is recorded to the flash memory **62** by the micro-controller **61**. Post-monitoring, the actigraphy data is temporally matched to the ECG data to provide the proper physiological context to the sensed event occurrence. As a result, the three-axis actigraphy signal is turned into an actionable event occurrence that is provided, through conversion by the middleware, to third party post-monitoring analysis programs, along with the ECG recordings contemporaneous to the event occurrence. Other types of processing of the other physiological data (or other information) are possible.

Thus, during execution of the middleware, any other physiological data (or other information) that has been embedded into the recorded ECG monitoring data is read (step **156**) and time-correlated to the time frame of the ECG signals that occurred at the time that the other physiological data (or other information) was noted (step **157**). Finally, the ECG datum, signal gain adjusted, if appropriate, and other physiological data, if applicable and as time-correlated, are stored in a format suitable to the backend software (step **158**) used in post-monitoring analysis.

In a further embodiment, the other physiological data, if apropos, is embedded within an unused ECG track. For example, the SCP-ENG standard allows multiple ECG channels to be recorded into a single ECG record. The monitor recorder **14**, though, only senses one ECG channel. The other physiological data can be stored into an additional ECG channel, which would otherwise be zero-padded or altogether omitted. The backend software would then be able to read the other physiological data in context with the single channel of ECG monitoring data recorded by the monitor recorder **14**, provided the backend software implemented changes necessary to interpret the other physiological data. Still other forms of embedding of the other physiological data with formatted ECG monitoring data, or of providing the other physiological data in a separate manner, are possible.

Processing continues (step **159**) for each remaining ECG datum, after which the processing loop is exited and execution terminates. Still other operations and steps are possible.

While the invention has been particularly shown and described as referenced to the embodiments thereof, those skilled in the art will understand that the foregoing and other changes in form and detail may be made therein without departing from the spirit and scope.

What is claimed is:

1. A wearable electrocardiography monitoring device, comprising:

a flexible backing including a strip comprising:

a first face and a second face, wherein a portion of the first face is covered in adhesive to adhere the strip to skin of a patient,

a first end section,

a second end section opposite the first end section, and

a mid-section between the first end section and the second end section;

a flexible circuit mounted to the second face of the strip, the flexible circuit comprising a first circuit trace and a second circuit trace;

a first electrocardiographic electrode and a second electrocardiographic electrode, wherein the first electrocardiographic electrode and the second electrocardiographic electrode are configured to sense electrocardiographic signals, wherein the first electrocardiographic electrode and the second electrocardiographic electrode are coupled to the flexible circuit, wherein the first electrocardiographic electrode is conductively exposed at the first face along the first end section of the strip, wherein the second electrocardiographic electrode is conductively exposed at the first face along the second end section of the strip, wherein the first circuit trace is electrically coupled to the first electrocardiographic electrode, and wherein the second circuit trace is electrically coupled to the second electrocardiographic electrode;

a battery;

a wireless transceiver;

a button configured to be pressed to mark an event;

a sealed housing having rounded edges on a top surface, wherein the sealed housing is coupled to the flexible backing, and wherein the sealed housing includes a processor, wherein the processor is electrically coupled to the first electrocardiographic electrode, the second electrocardiographic electrode, and the battery, wherein the processor is configured to process the electrocardiographic signals sensed via the first electrocardiographic electrode and the second electrocardiographic electrode.

2. The wearable electrocardiography monitoring device of claim **1**, wherein the mid-section comprises a first edge parallel to a second edge.

3. The wearable electrocardiography monitoring device of claim **1**, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.

4. The wearable electrocardiography monitoring device of claim **1**, wherein the electrocardiographic signals are converted to a different format.

5. The wearable electrocardiography monitoring device of claim **4**, wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.

6. The wearable electrocardiography monitoring device of claim **1**, wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.

7. The wearable electrocardiography monitoring device of claim **1**, wherein the battery is vertically aligned with the wireless transceiver.

8. A wearable electrocardiography monitoring device, comprising:

a flexible backing including a strip comprising:

a first face and a second face, wherein a portion of the first face is covered in adhesive to adhere the strip to skin of a patient,

a first end section,

a second end section opposite the first end section, and

a mid-section between the first end section and the second end section, wherein the mid-section is narrower than the first end section and the second end section;

a flexible circuit mounted to the second face of the strip, the flexible circuit comprising a first circuit trace and a second circuit trace;

a first electrocardiographic electrode and a second electrocardiographic electrode, wherein the first electrocardiographic electrode and the second electrocardiographic electrode are configured to sense electrocardiographic signals, wherein the first electrocardiographic electrode and the second electrocardiographic electrode are coupled to the flexible circuit, wherein the first electrocardiographic electrode is conductively exposed at the first face along the first end section of the strip, wherein the second electrocardiographic electrode is conductively exposed at the first face along the second end section of the strip, wherein the first circuit trace is electrically coupled to the first electrocardiographic electrode, wherein the second circuit trace is electrically coupled to the second electrocardiographic electrode, and wherein the first electrocardiographic electrode includes an inline resistor;

a battery;

a wireless transceiver;

a button configured to be pressed to mark an event;

a sealed housing having rounded edges on a top surface, wherein the sealed housing is coupled to the flexible backing, and wherein the sealed housing includes a processor, wherein the processor is electrically coupled to the first electrocardiographic electrode, the second electrocardiographic electrode, and the battery, wherein the processor is configured to process the electrocardiographic signals sensed via the first electrocardiographic electrode and the second electrocardiographic electrode.

9. The wearable electrocardiography monitoring device of claim **8**, wherein the battery is vertically aligned with the sealed housing.

10. The wearable electrocardiography monitoring device of claim **8**, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.

11. The wearable electrocardiography monitoring device of claim **8**, wherein the electrocardiographic signals are converted to a different format.

12. The wearable electrocardiography monitoring device of claim **11**, wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.

13. The wearable electrocardiography monitoring device of claim **8**, wherein the adhesive covering the portion of the first face of the strip is provided on the first end section and the second end section only.

14. The wearable electrocardiography monitoring device of claim **8**, wherein the battery is vertically aligned with the wireless transceiver.

15. A wearable electrocardiography monitoring device, comprising:

a flexible backing comprising:

a first face and a second face, wherein the first face includes an adhesive to adhere the flexible backing to skin of a patient;

a first end section opposite a second end section, wherein a mid-section is disposed between the first end section and the second end section, wherein the mid-section is narrower than the first end section and the second end section, and wherein the mid-section includes a first edge parallel to a second edge; and

a flexible circuit, wherein the flexible circuit comprises a first circuit trace and a second circuit trace on the second face of the flexible backing;

a first electrocardiographic electrode configured to sense electrocardiographic signals, wherein the first electrocardiographic electrode is conductively exposed at the first face along the second end section of the flexible backing, and wherein the first electrocardiographic electrode is electrically coupled to the first circuit trace;

a second electrocardiographic electrode configured to sense electrocardiographic signals, wherein the second electrocardiographic electrode is conductively exposed at the first face along the first end section of the flexible backing, and wherein the second electrocardiographic electrode is electrically coupled to the second circuit trace;

a sealed housing having rounded edges on a top surface, wherein the sealed housing is coupled to the flexible backing, wherein the sealed housing includes a processor, wherein the processor is electrically coupled to the first electrocardiographic electrode and the second electrocardiographic electrode, wherein the processor is configured to process the electrocardiographic signals sensed via the first electrocardiographic electrode and the second electrocardiographic electrode;

a button disposed on the top surface of the sealed housing, wherein the button is configured to be pressed to mark an event;

a battery disposed between the processor and the skin of the patient, the battery configured to provide power to the processor of the sealed housing; and

a wireless transceiver configured to communicate at least a portion of the electrocardiographic signals.

16. The wearable electrocardiography monitoring device of claim **15**, wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth.

17. The wearable electrocardiography monitoring device of claim **15**, wherein the electrocardiographic signals are converted to a different format.

18. The wearable electrocardiography monitoring device of claim **17**, wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.

19. The wearable electrocardiography monitoring device of claim **15**, wherein the adhesive covering the portion of the first face is provided on the first end section and the second end section only.

20. The wearable electrocardiography monitoring device of claim **15**, wherein the battery is vertically aligned with the wireless transceiver.

21. The wearable electrocardiography monitoring device of claim **15**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format,

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format,

wherein the adhesive covering the portion of the first face is provided on the first end section and the second end section only, and

wherein the battery is vertically aligned with the wireless transceiver.

22. The wearable electrocardiography monitoring device of claim **15**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to a different format,

wherein the adhesive covering the portion of the first face is provided on the first end section and the second end section only, and

wherein the battery is vertically aligned with the wireless transceiver.

23. The wearable electrocardiography monitoring device of claim **15**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format,

wherein the adhesive covering the portion of the first face is provided on the first end section and the second end section only, and

wherein the battery is vertically aligned with the wireless transceiver.

24. The wearable electrocardiography monitoring device of claim **15**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format,

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format, and

wherein the battery is vertically aligned with the wireless transceiver.

25. The wearable electrocardiography monitoring device of claim **15**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format,

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format, and

wherein the adhesive covering the portion of the first face is provided on the first end section and the second end section only.

26. The wearable electrocardiography monitoring device of claim **15**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format, and

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to the different format.

27. The wearable electrocardiography monitoring device of claim **15**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format, and

wherein the adhesive covering the portion of the first face is provided on the first end section and the second end section only.

28. The wearable electrocardiography monitoring device of claim **15**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are converted to a different format, and

wherein the battery is vertically aligned with the wireless transceiver.

29. The wearable electrocardiography monitoring device of claim **15**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to a different format, and

wherein the adhesive covering the portion of the first face is provided on the first end section and the second end section only.

30. The wearable electrocardiography monitoring device of claim **15**,

wherein the wireless transceiver is configured to communicate with an external device via Wi-Fi, mobile phone communication standards, or Bluetooth,

wherein the electrocardiographic signals are retrieved by one of a server, a client computer, and a mobile device via the wireless transceiver after the electrocardiographic signals are converted to a different format, and

wherein the battery is vertically aligned with the wireless transceiver.

* * * * *

US012285261B2

(12) **United States Patent**
Bishay et al.

(10) **Patent No.: US 12,285,261 B2**
(45) **Date of Patent: *Apr. 29, 2025**

(54) **MOISTURE-RESISTANT ELECTROCARDIOGRAMY MONITOR**

(71) Applicant: **Bardy Diagnostics, Inc.**, Bellevue, WA (US)

(72) Inventors: **Jon Mikalson Bishay**, Lexington, KY (US); **Jason Felix**, Vashon Island, WA (US); **Gust H. Bardy**, Carnation, WA (US)

(73) Assignee: **Bardy Diagnostics, Inc.**

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 49 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **18/318,641**

(22) Filed: **May 16, 2023**

(65) **Prior Publication Data**

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Related U.S. Application Data

(63) Continuation of application No. 17/959,174, filed on Oct. 3, 2022, now Pat. No. 11,653,869, which is a (Continued)

(51) **Int. Cl.**
A61B 5/05 (2021.01)
A61B 5/00 (2006.01)
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(52) **U.S. Cl.**
CPC ***A61B 5/349*** (2021.01); ***A61B 5/0006*** (2013.01); ***A61B 5/0205*** (2013.01); ***A61B 5/259*** (2021.01);
(Continued)

(58) **Field of Classification Search**
CPC . A61B 5/04085; A61B 5/0006; A61B 5/6833; A61B 5/04087; A61B 5/0402;
(Continued)

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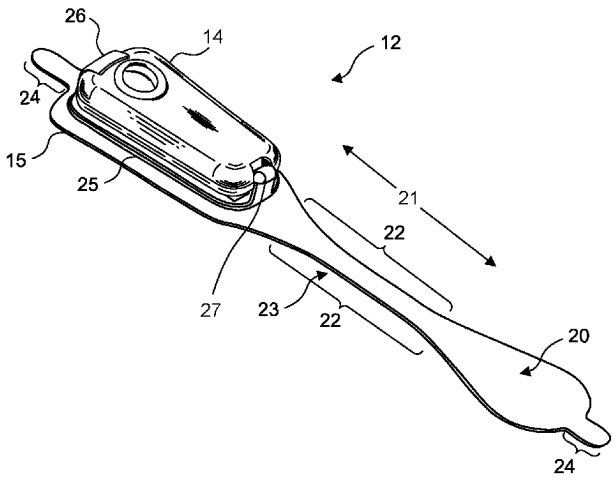
Assistant Examiner — Brian M Antiskay
(74) *Attorney, Agent, or Firm* — K&L Gates LLP

(57) **ABSTRACT**

Physiological monitoring can be provided through a lightweight wearable monitor that includes two components, a flexible extended wear electrode patch and a reusable monitor recorder that removably snaps into a receptacle on the electrode patch. The wearable monitor sits centrally on the patient's chest along the sternum oriented top-to-bottom. The placement of the wearable monitor in a location at the sternal midline, with its unique narrow "hourglass"-like shape, significantly improves the ability of the wearable monitor to cutaneously sense cardiac electrical potential signals, particularly the P-wave and the QRS interval signals indicating ventricular activity in the ECG waveforms. In particular, the ECG electrodes on the electrode patch are tailored to be positioned axially along the midline of the sternum for capturing action potential propagation in an orientation that corresponds to the aVF lead used in a
(Continued)



conventional 12-lead ECG that is used to sense positive or upright P-waves.

19 Claims, 15 Drawing Sheets

Related U.S. Application Data

continuation of application No. 16/782,951, filed on Feb. 5, 2020, now Pat. No. 11,457,852, which is a continuation of application No. 16/404,562, filed on May 6, 2019, now Pat. No. 10,561,328, which is a continuation of application No. 16/174,122, filed on Oct. 29, 2018, now Pat. No. 10,278,606, which is a continuation of application No. 15/645,708, filed on Jul. 10, 2017, now Pat. No. 10,111,601, which is a continuation of application No. 14/488,230, filed on Sep. 16, 2014, now Pat. No. 9,700,227, which is a continuation-in-part of application No. 14/080,725, filed on Nov. 14, 2013, now Pat. No. 9,730,593.

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(51) **Int. Cl.**

A61B 5/0205	(2006.01)
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CPC ***A61B 5/282*** (2021.01); ***A61B 5/6823*** (2013.01); *A61B 5/7225* (2013.01); *A61B 2560/0406* (2013.01); *A61B 2560/0443* (2013.01)

(58) **Field of Classification Search**

CPC A61B 2018/00351; A61N 1/04; A61N 1/0484

USPC 600/372, 382, 384, 386, 388, 390–393, 600/508–509

See application file for complete search history.

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[Corrected] Chart C-2 Invalidity Contentions: U.S. Pat. No. 11,051,743; Case No. 22-351-CJB (Delaware); Invalidity of U.S. Pat. No. 11,051,743 by U.S. Pat. Pub. No. 2011/0077497 ("Oster") and U.S. Pat. No. 11,116,447 ("Yang"); Oct. 25, 2023; 22 pages.

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Fig. 1.

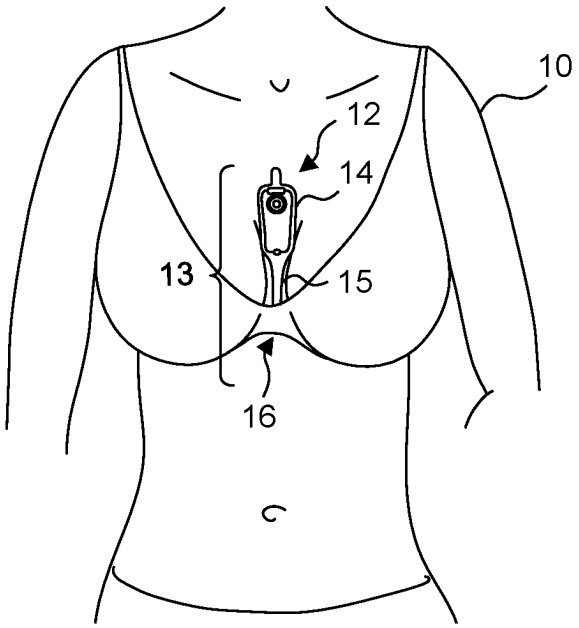


Fig. 2.

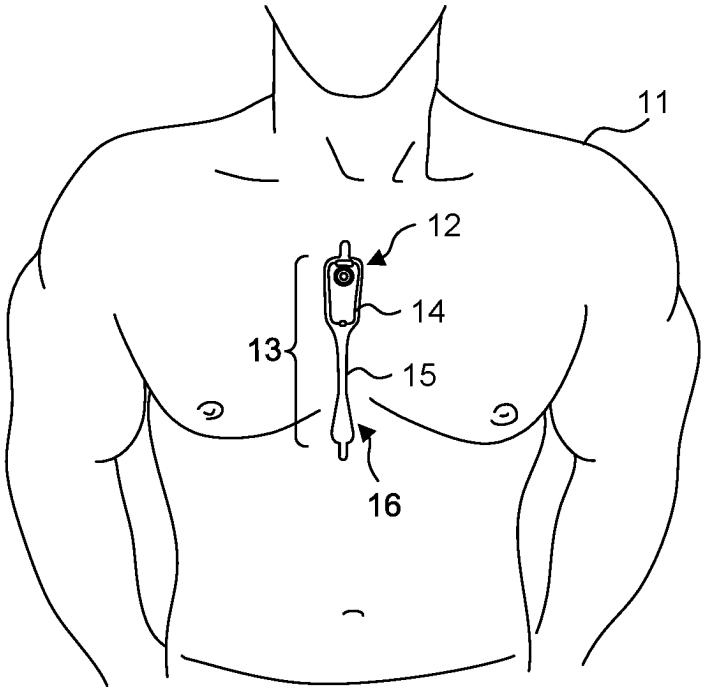


Fig. 3.

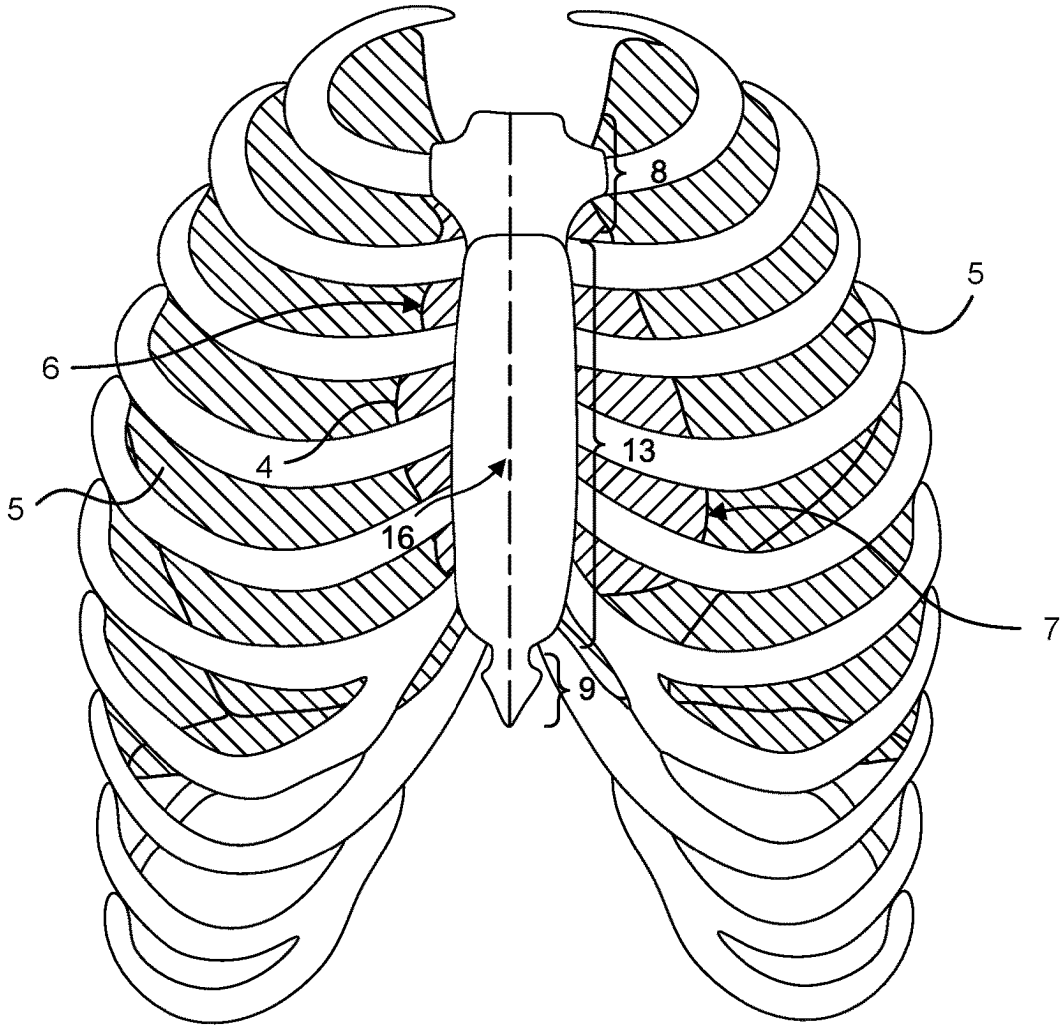


Fig. 4.

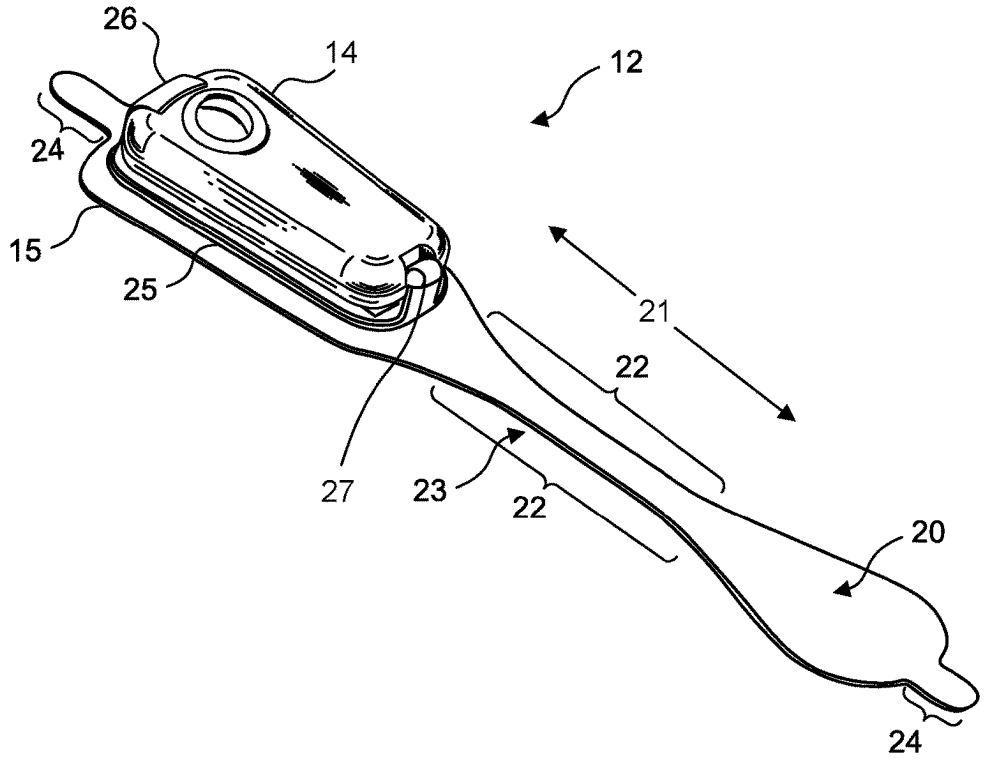


Fig. 5.

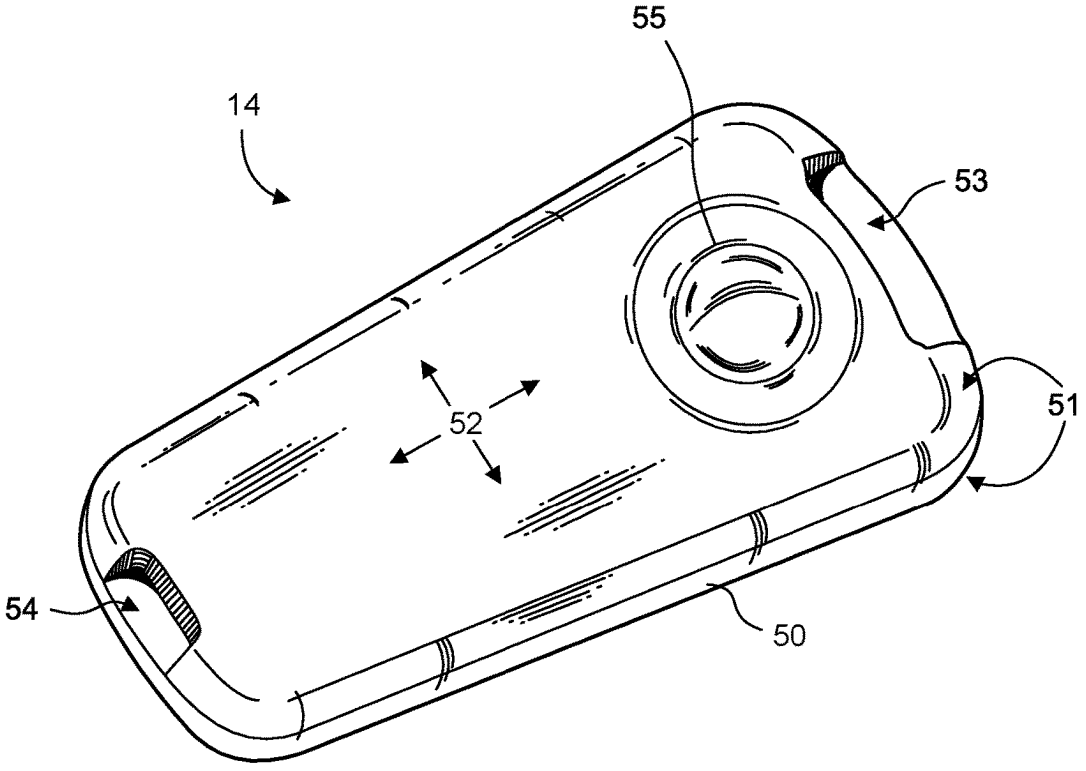


Fig. 6.

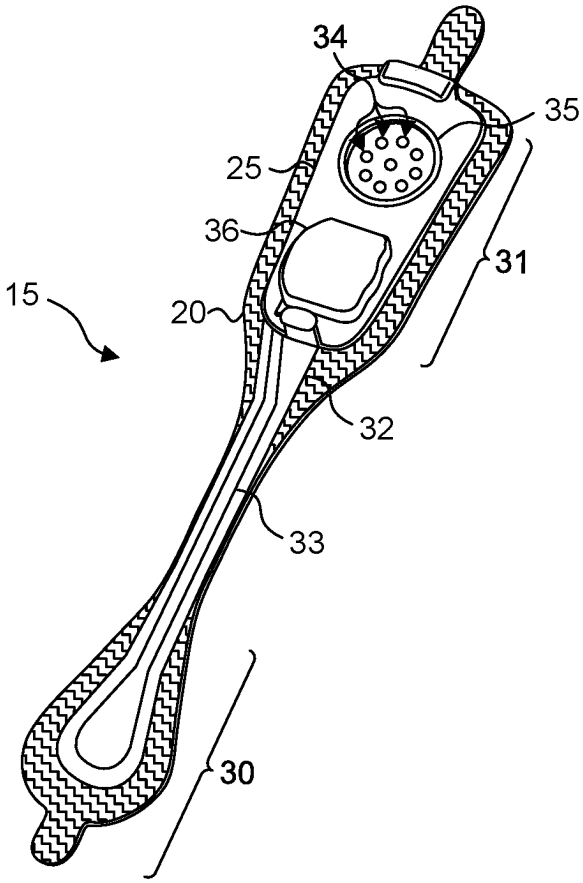


Fig. 7.

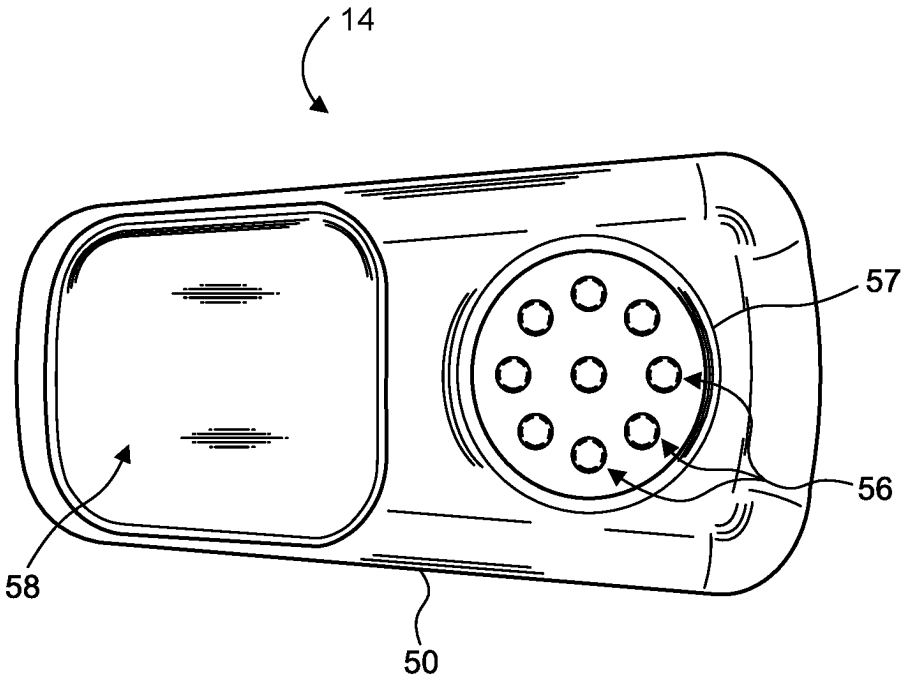


Fig. 8.

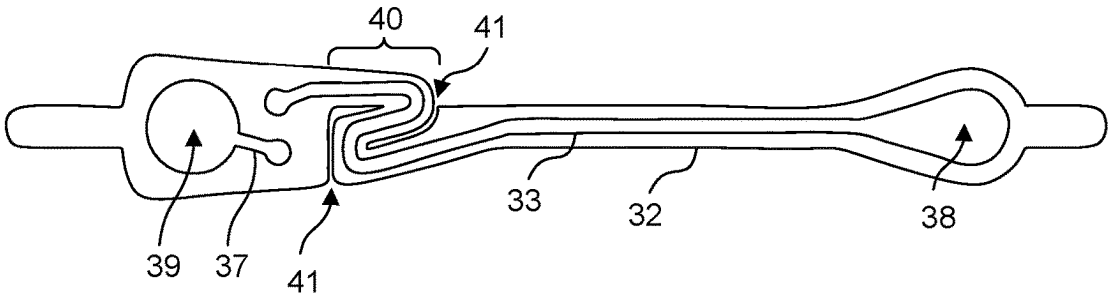


Fig. 9.

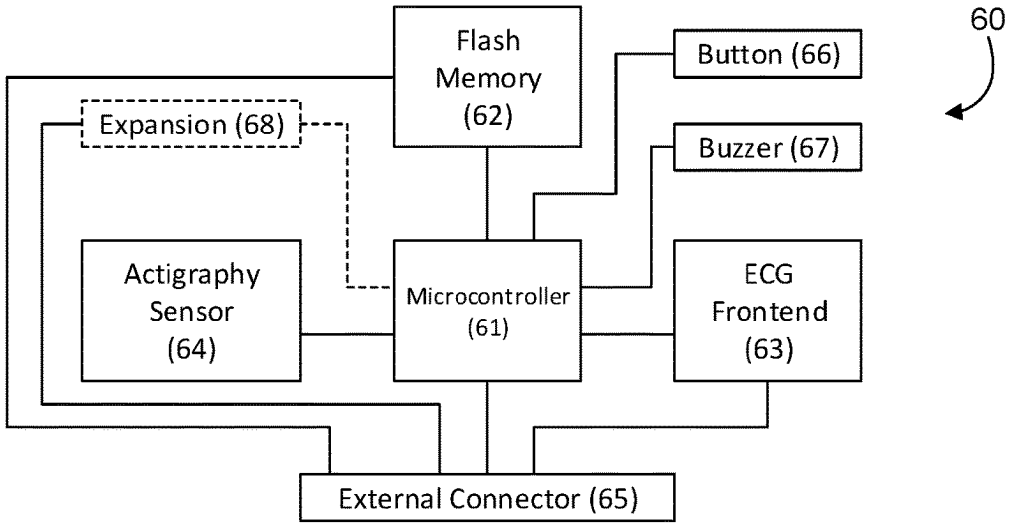
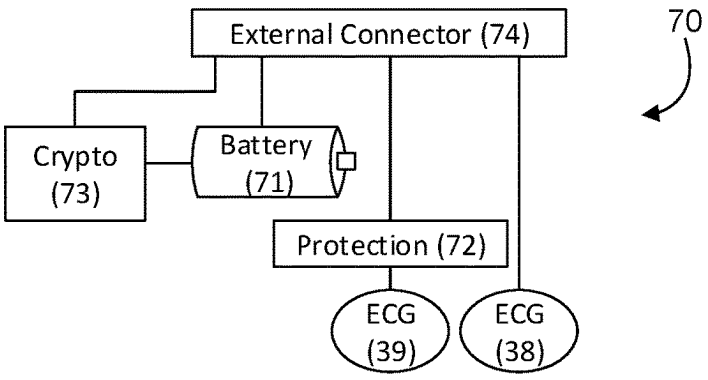


Fig. 10.



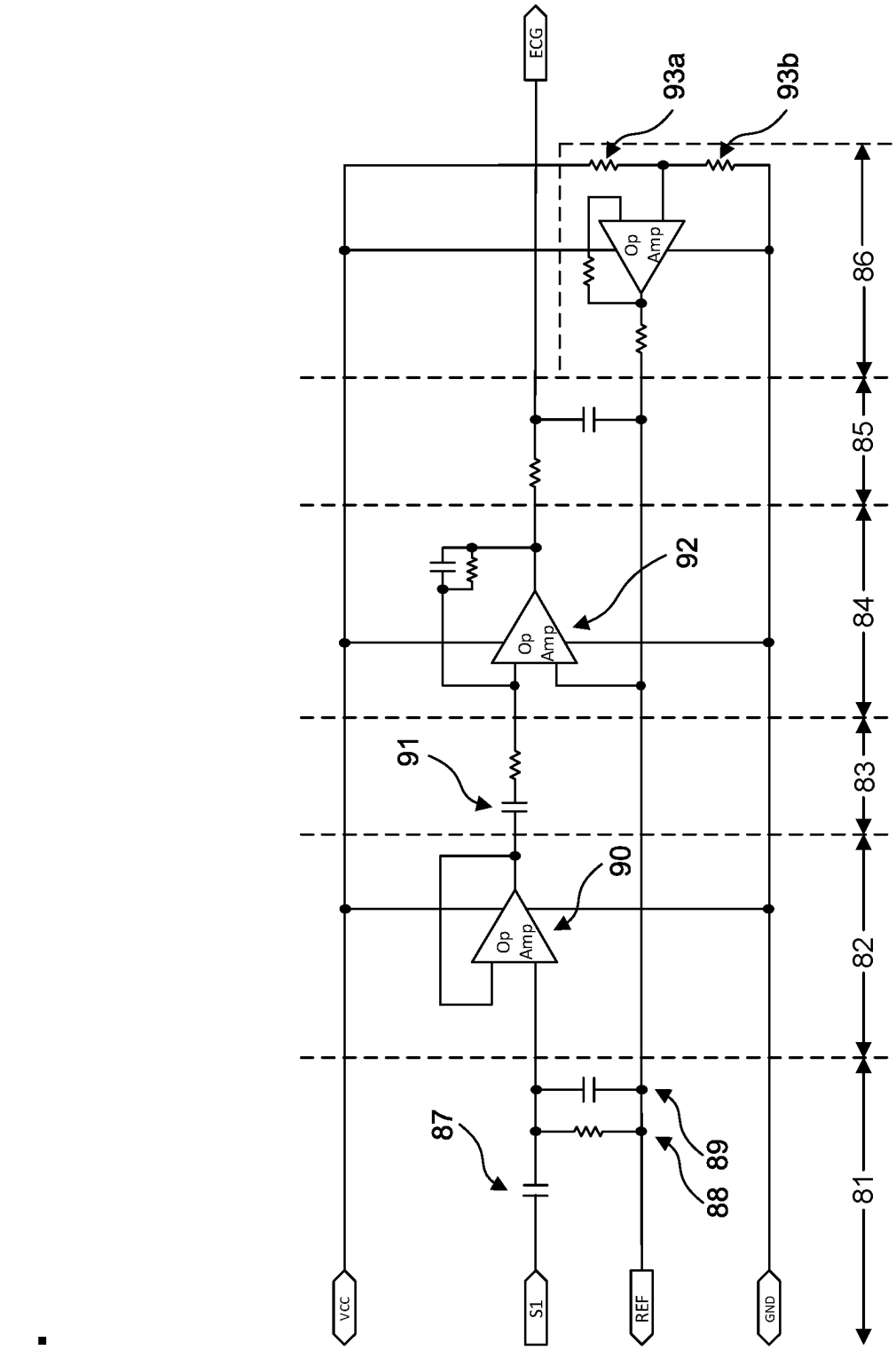

ECG
93a
93b
Op Amp
86
85
92
Op Amp
84
91
83
90
Op Amp
82
87
89
88
81
VCC
S1
REF
GND

Fig. 11.

80

Fig. 12.

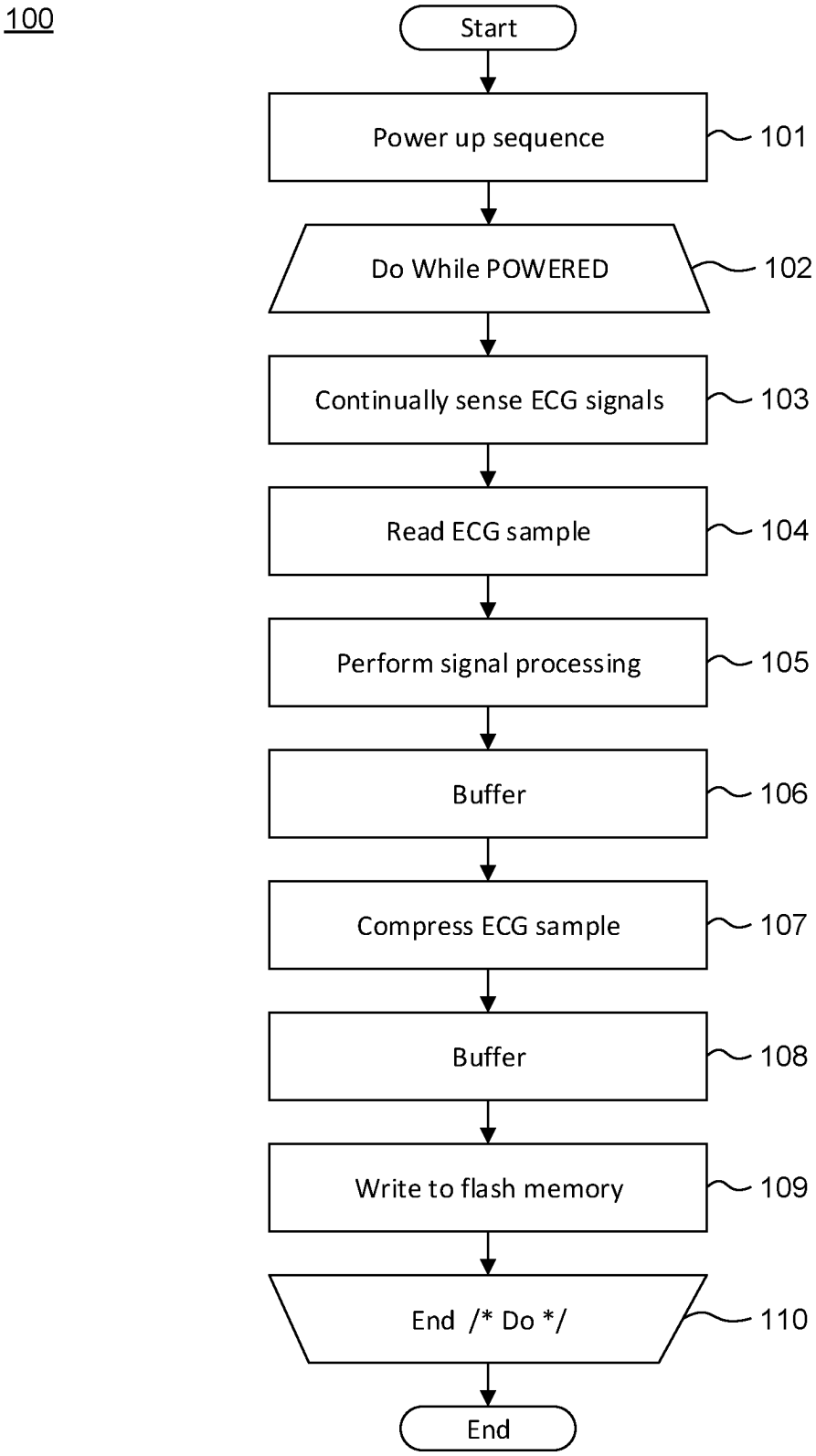

100
Start
Power up sequence
101
Do While POWERED
102
Continually sense ECG signals
103
Read ECG sample
104
Perform signal processing
105
Buffer
106
Compress ECG sample
107
Buffer
108
Write to flash memory
109
End /* Do */
110
End

Fig. 13.

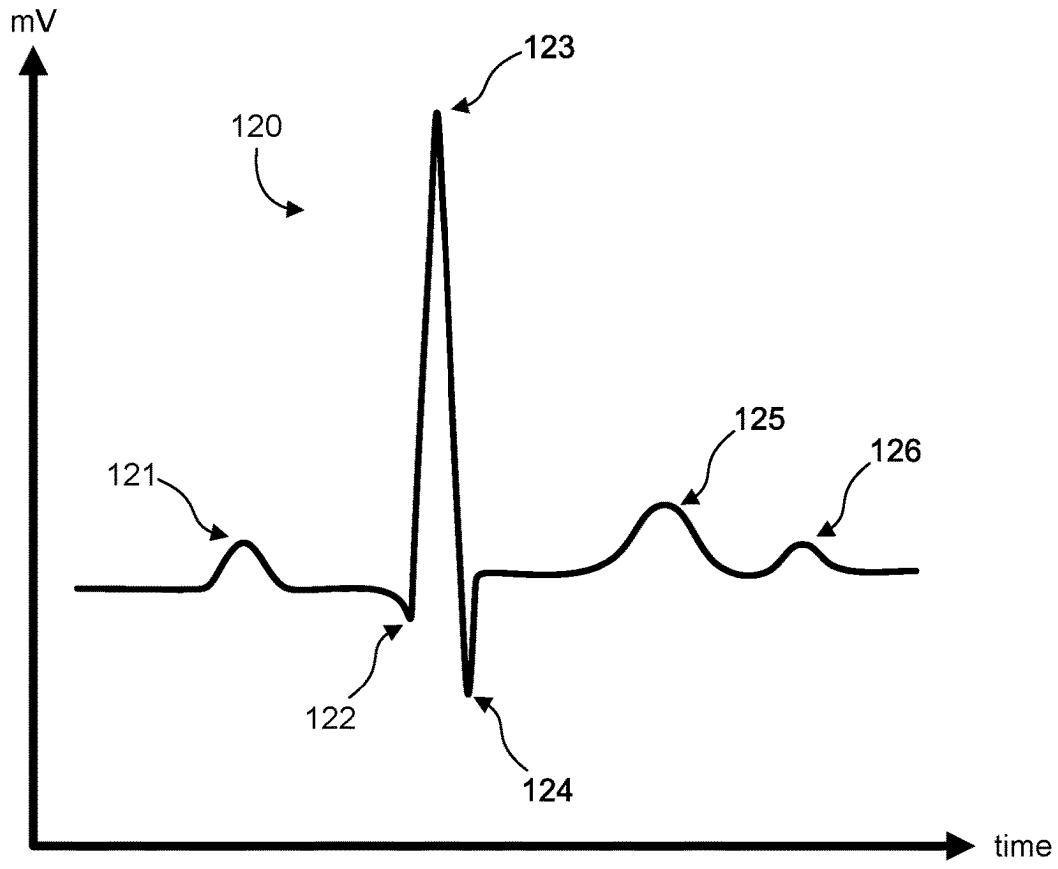


Fig. 14.

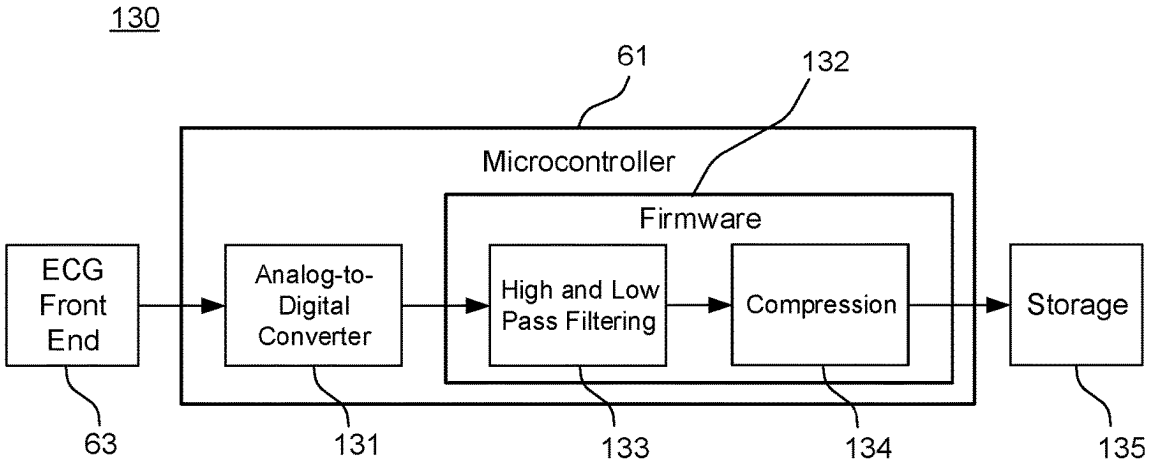

130
61
132
Microcontroller
Firmware
ECG Front End
Analog-to-Digital Converter
High and Low Pass Filtering
Compression
Storage
63
131
133
134
135

Fig. 15.

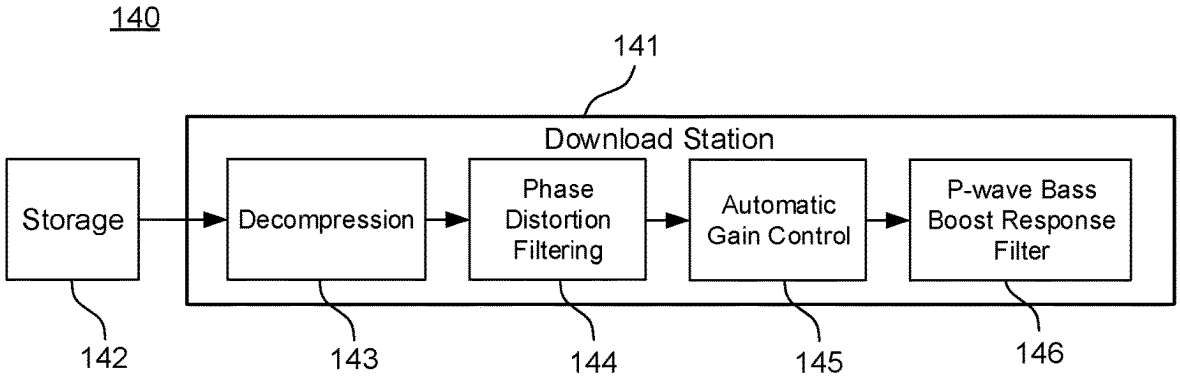

140
141
Download Station
Storage
Decompression
Phase Distortion Filtering
Automatic Gain Control
P-wave Bass Boost Response Filter
142
143
144
145
146

Fig. 16A.

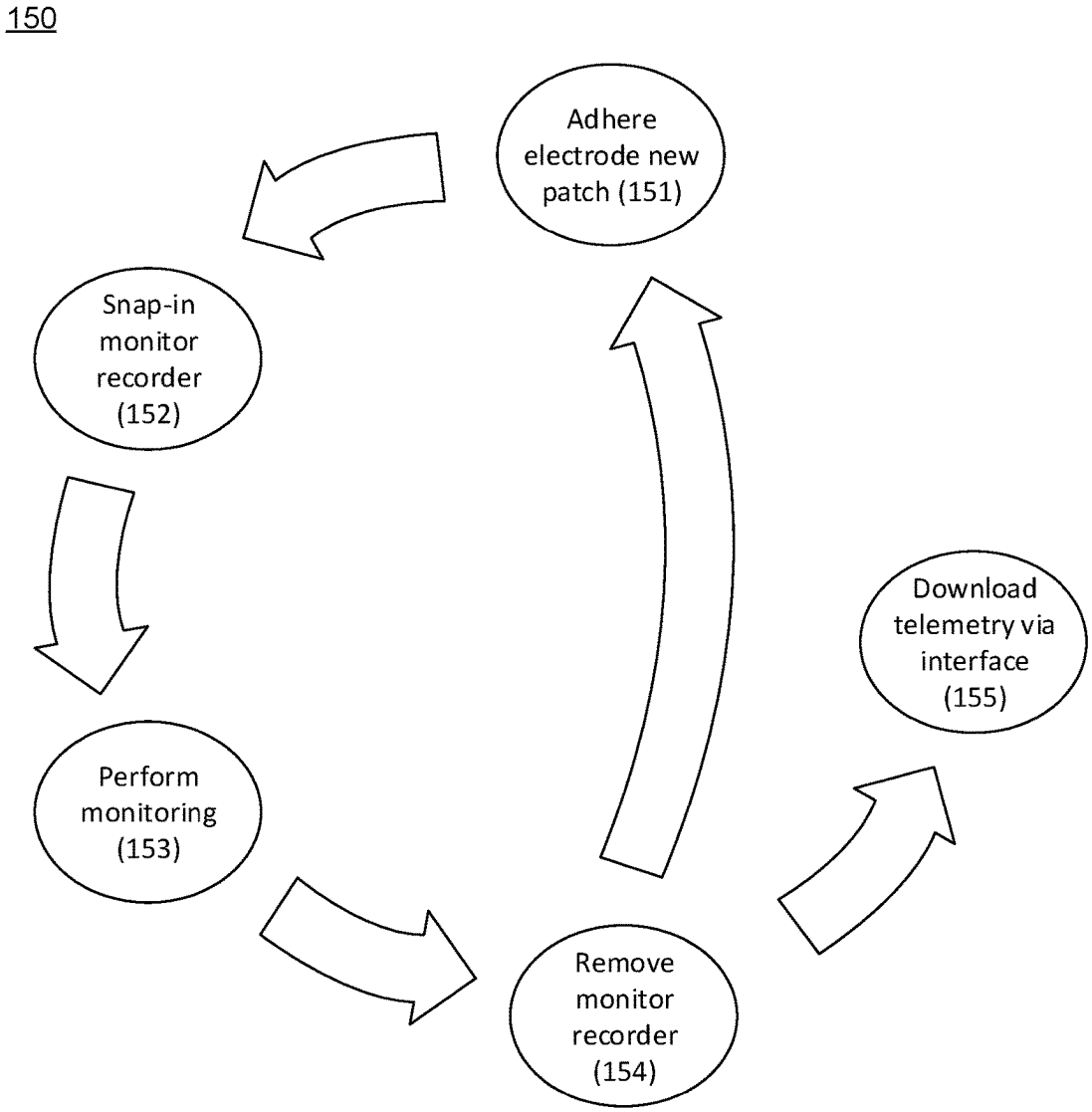

150
Adhere electrode new patch (151)
Snap-in monitor recorder (152)
Perform monitoring (153)
Remove monitor recorder (154)
Download telemetry via interface (155)

Fig. 16B.

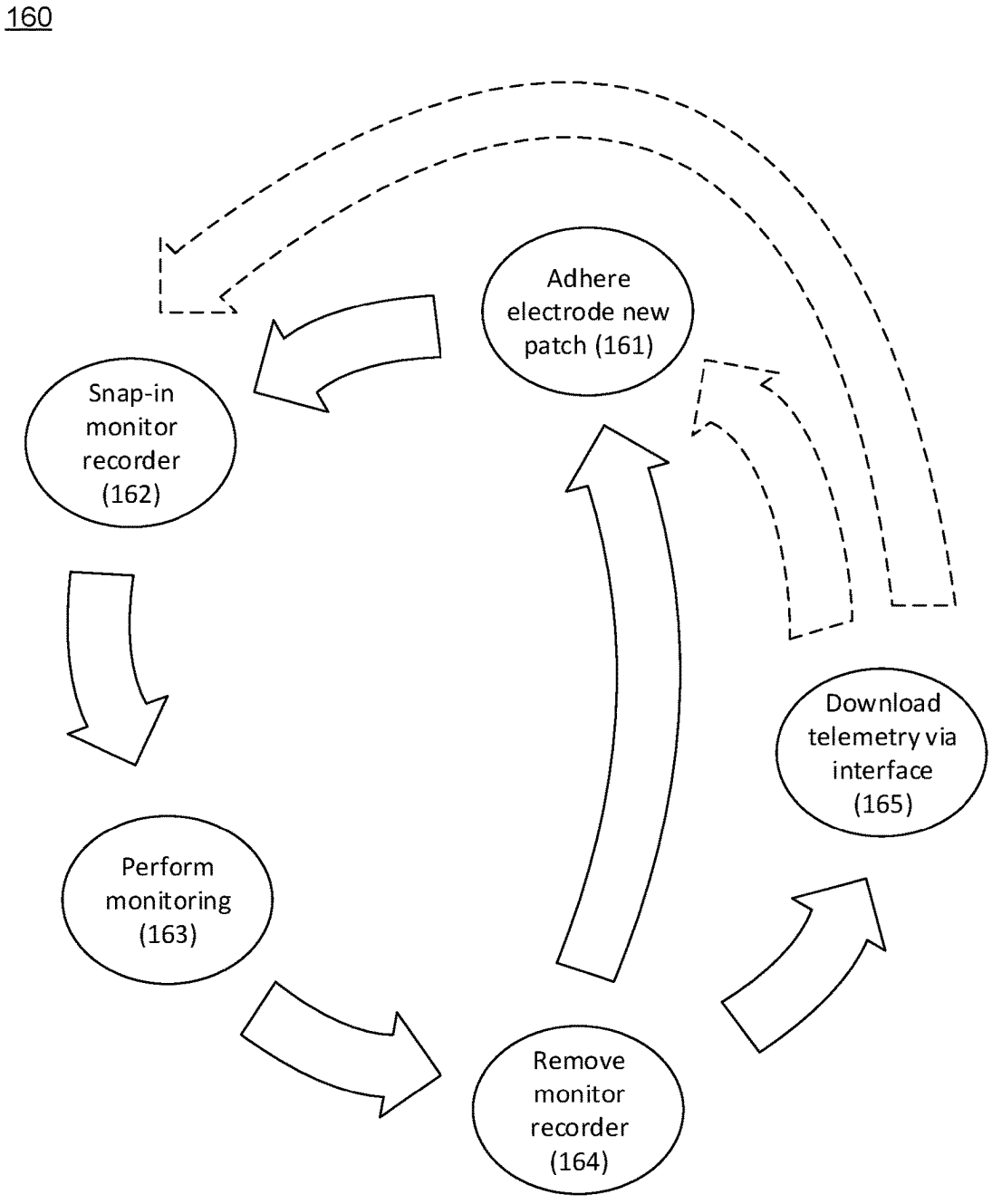

160
Adhere electrode new patch (161)
Snap-in monitor recorder (162)
Download telemetry via interface (165)
Perform monitoring (163)
Remove monitor recorder (164)

Fig. 16C.

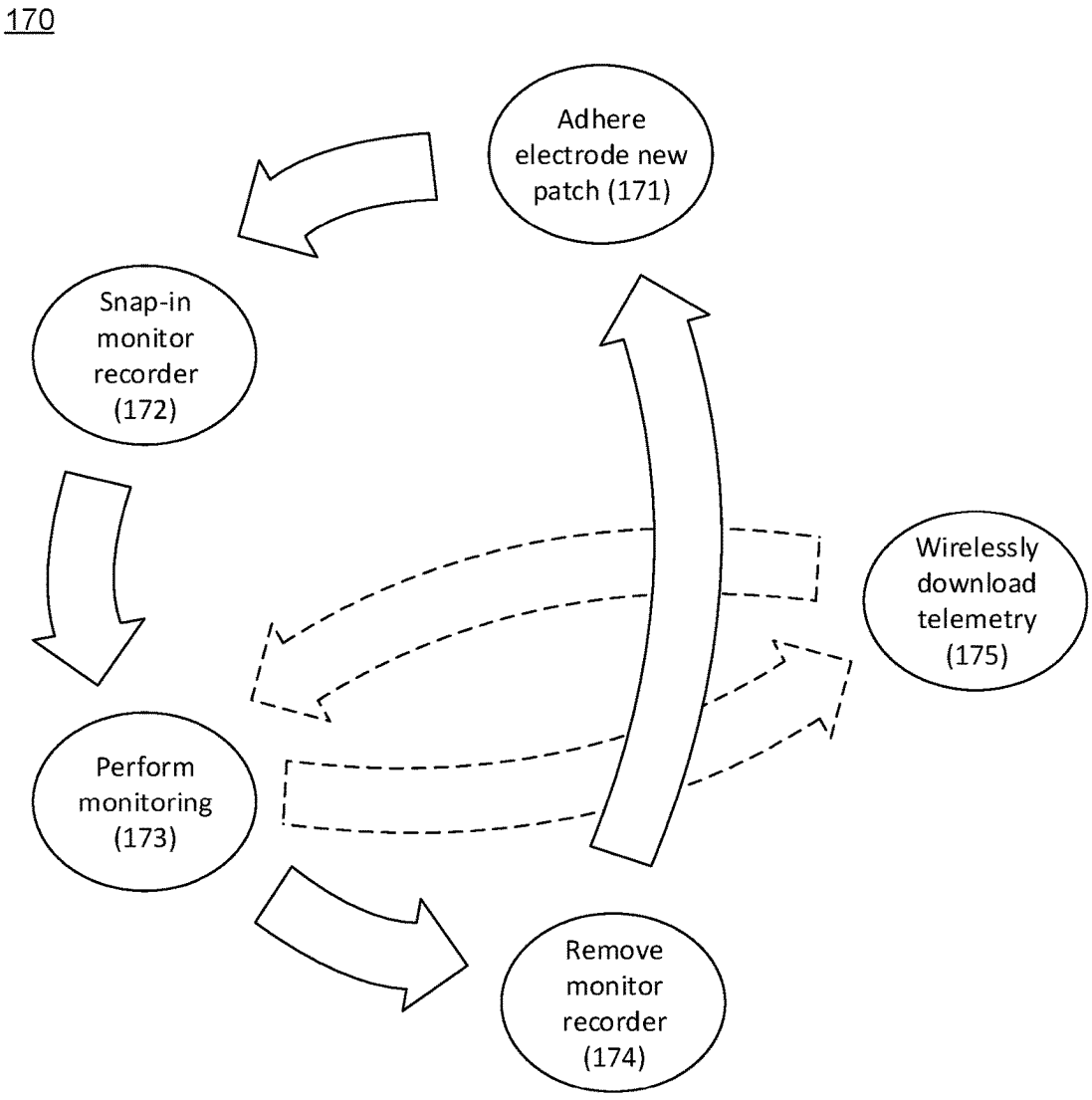

170
Adhere electrode new patch (171)
Snap-in monitor recorder (172)
Wirelessly download telemetry (175)
Perform monitoring (173)
Remove monitor recorder (174)

Fig. 17.

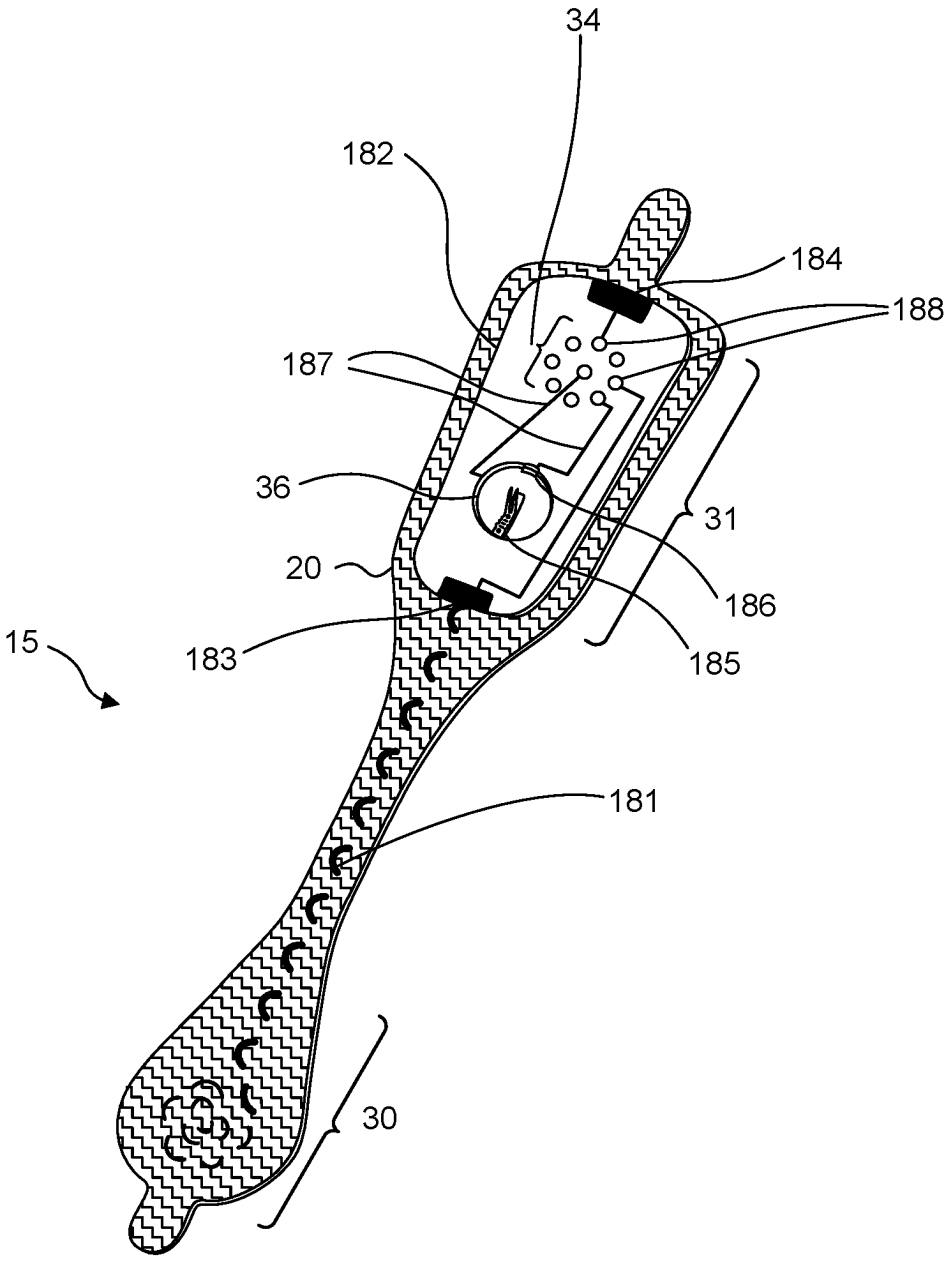


Fig. 18.

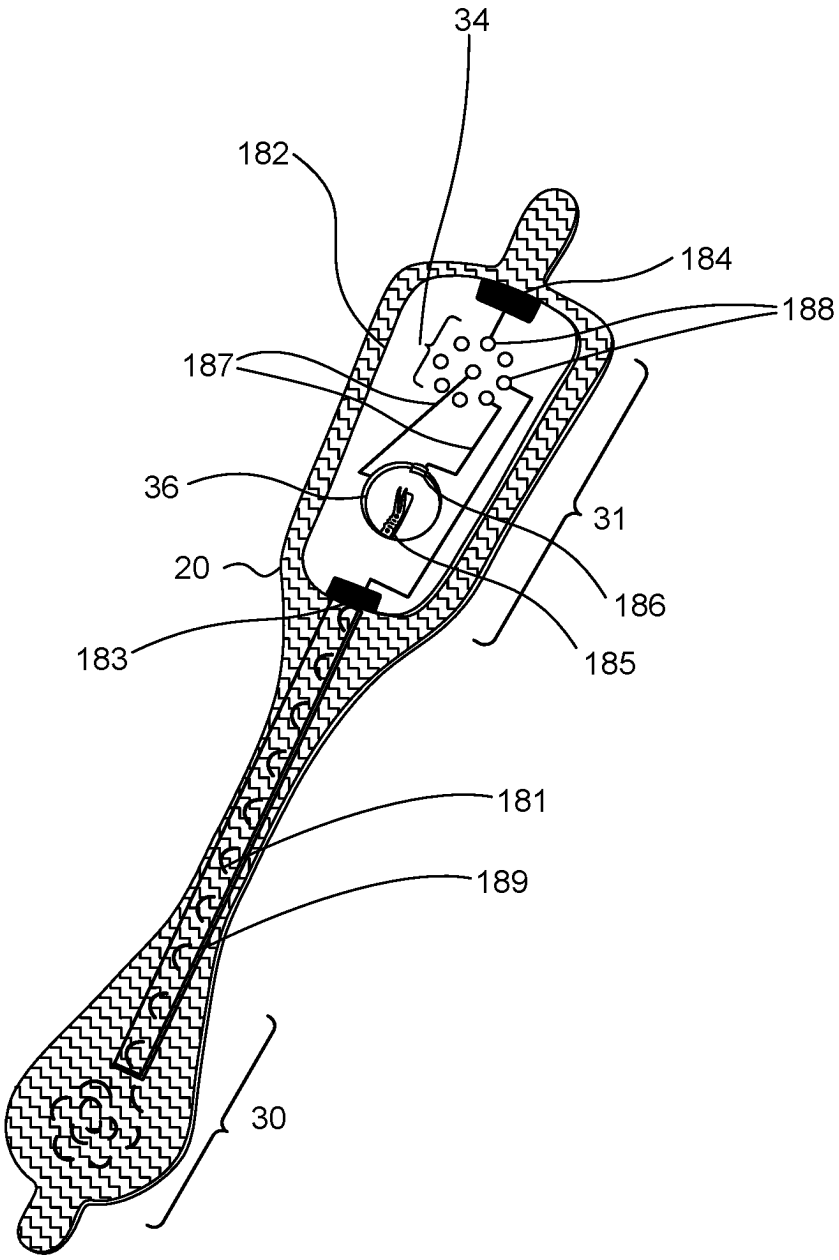


Fig. 19.

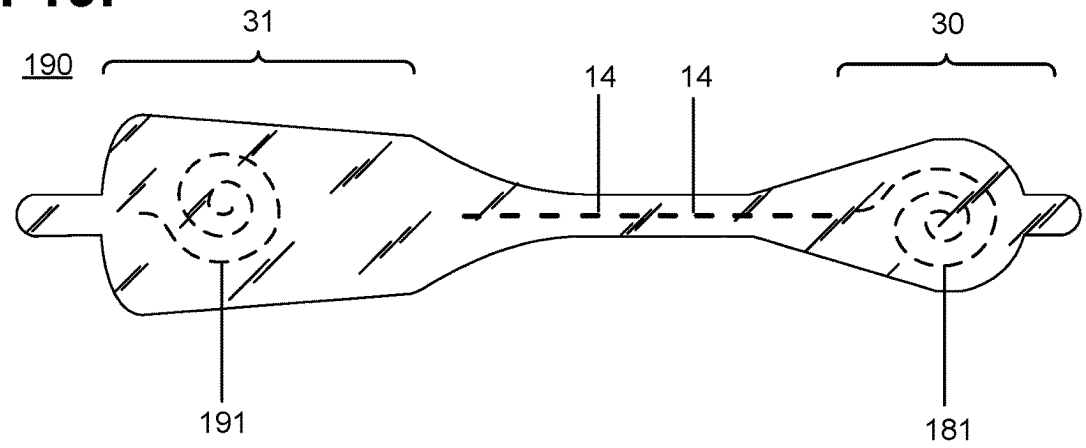


Fig. 20.

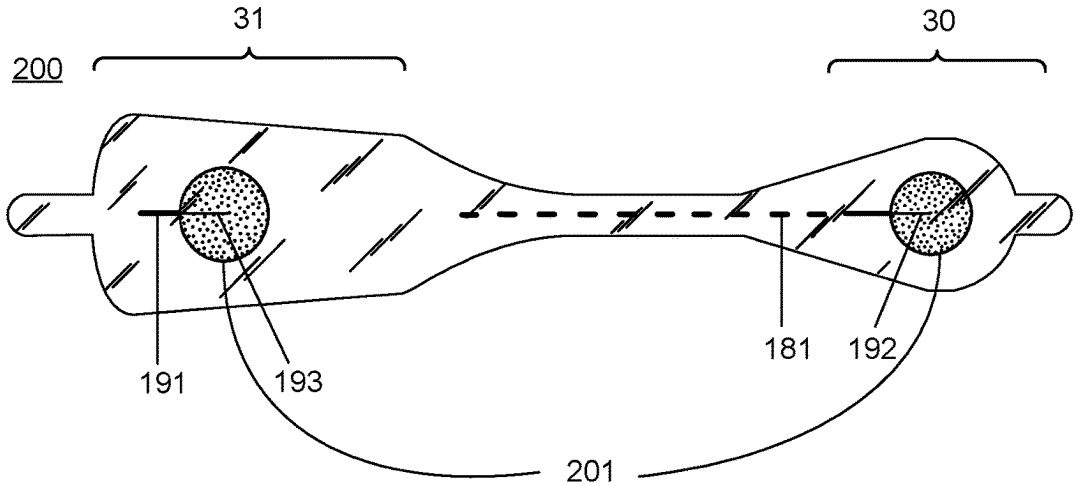
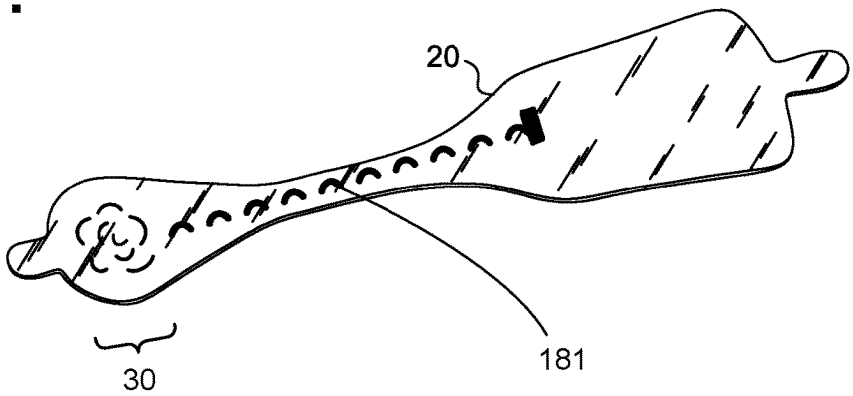


Fig. 21.



MOISTURE-RESISTANT ELECTROCARDIOGRAMY MONITOR

FIELD

This application relates in general to electrocardiographic monitoring and, in particular, to a moisture-resistant electrocardiography monitor.

BACKGROUND

The first electrocardiogram (ECG) was invented by a Dutch physiologist, Willem Einthoven, in 1903, who used a string galvanometer to measure the electrical activity of the heart. Generations of physicians around the world have since used ECGs, in various forms, to diagnose heart problems and other potential medical concerns. Although the basic principles underlying Dr. Einthoven's original work, including his naming of various waveform deflections (Einthoven's triangle), are still applicable today, ECG machines have evolved from his original three-lead ECG, to ECGs with unipolar leads connected to a central reference terminal starting in 1934, to augmented unipolar leads beginning in 1942, and finally to the 12-lead ECG standardized by the American Heart Association in 1954 and still in use today. Further advances in portability and computerized interpretation have been made, yet the electronic design of the ECG recording apparatuses has remained fundamentally the same for much of the past 40 years.

Essentially, an ECG measures the electrical signals emitted by the heart as generated by the propagation of the action potentials that trigger depolarization of heart fibers. Physiologically, transmembrane ionic currents are generated within the heart during cardiac activation and recovery sequences. Cardiac depolarization originates high in the right atrium in the sinoatrial (SA) node before spreading leftward towards the left atrium and inferiorly towards the atrioventricular (AV) node. After a delay occasioned by the AV node, the depolarization impulse transits the Bundle of His and moves into the right and left bundle branches and Purkinje fibers to activate the right and left ventricles.

During each cardiac cycle, the ionic currents create an electrical field in and around the heart that can be detected by ECG electrodes placed on the skin. Cardiac electrical activity is then visually represented in an ECG trace by PQRSTU-waveforms. The P-wave represents atrial electrical activity, and the QRSTU components represent ventricular electrical activity. Specifically, a P-wave represents atrial depolarization, which causes atrial contraction.

P-wave analysis based on ECG monitoring is critical to accurate cardiac rhythm diagnosis and focuses on localizing the sites of origin and pathways of arrhythmic conditions. P-wave analysis is also used in the diagnosis of other medical disorders, including imbalance of blood chemistry. Cardiac arrhythmias are defined by the morphology of P-waves and their relationship to QRS intervals. For instance, atrial fibrillation (AF), an abnormally rapid heart rhythm, can be confirmed by an absence of P-waves and an irregular ventricular rate. Similarly, sinoatrial block is characterized by a delay in the onset of P-waves, while junctional rhythm, an abnormal heart rhythm resulting from impulses coming from a locus of tissue in the area of the AV node, usually presents without P-waves or with inverted P-waves. Also, the amplitudes of P-waves are valuable for diagnosis. The presence of broad, notched P-waves can indicate left atrial enlargement. Conversely, the presence of tall, peaked P-waves can indicate right atrial enlargement. Finally, P-waves with increased amplitude can indicate hypokalemia, caused by low blood potassium, whereas P-waves with decreased amplitude can indicate hyperkalemia, caused by elevated blood potassium.

Cardiac rhythm disorders may present with lightheadedness, fainting, chest pain, hypoxia, syncope, palpitations, and congestive heart failure (CHF), yet rhythm disorders are often sporadic in occurrence and may not show up in-clinic during a conventional 12-second ECG. Continuous ECG monitoring with P-wave-centric action potential acquisition over an extended period is more apt to capture sporadic cardiac events. However, recording sufficient ECG and related physiological data over an extended period remains a significant challenge, despite an over 40-year history of ambulatory ECG monitoring efforts combined with no appreciable improvement in P-wave acquisition techniques since Dr. Einthoven's original pioneering work over a 110 years ago.

Electrocardiographic monitoring over an extended period provides a physician with the kinds of data essential to identifying the underlying cause of sporadic cardiac conditions, especially rhythm disorders, and other physiological events of potential concern. A 30-day observation period is considered the "gold standard" of monitoring, yet a 14-day observation period is currently pitched as being achievable by conventional ECG monitoring approaches. Realizing a 30-day observation period has proven unworkable with existing ECG monitoring systems, which are arduous to employ; cumbersome, uncomfortable and not user-friendly to the patient; and costly to manufacture and deploy. Still, if a patient's ECG could be recorded in an ambulatory setting over a prolonged time periods, particularly for more than 14 days, thereby allowing the patient to engage in activities of daily living, the chances of acquiring meaningful medical information and capturing an abnormal event while the patient is engaged in normal activities are greatly improved.

The location of the atria and their low amplitude, low frequency content electrical signals make P-waves difficult to sense, particularly through ambulatory ECG monitoring. The atria are located posteriorly within the chest, and their physical distance from the skin surface adversely affects current strength and signal fidelity. Cardiac electrical potentials measured dermally have an amplitude of only one-percent of the amplitude of transmembrane electrical potentials. The distance between the heart and ECG electrodes reduces the magnitude of electrical potentials in proportion to the square of change in distance, which compounds the problem of sensing low amplitude P-waves. Moreover, the tissues and structures that lie between the activation regions within the heart and the body's surface alter the cardiac electrical field due to changes in the electrical resistivity of adjacent tissues. Thus, surface electrical potentials, when even capable of being accurately detected, are smoothed over in aspect and bear only a general spatial relationship to actual underlying cardiac events, thereby complicating diagnosis. Conventional 12-lead ECGs attempt to compensate for weak P-wave signals by monitoring the heart from multiple perspectives and angles, while conventional ambulatory ECGs primarily focus on monitoring higher amplitude ventricular activity that can be readily sensed. Both approaches are unsatisfactory with respect to the P-wave and the accurate, medically actionable diagnosis of the myriad cardiac rhythm disorders that exist.

Additionally, maintaining continual contact between ECG electrodes and the skin after a day or two of ambulatory ECG monitoring has been a problem. Time, dirt, moisture, and other environmental contaminants, as well as perspira-

tion, skin oil, and dead skin cells from the patient's body, can get between an ECG electrode's non-conductive adhesive and the skin's surface. These factors adversely affect electrode adhesion and the quality of cardiac signal recordings. Furthermore, the physical movements of the patient and their clothing impart various compressional, tensile, bending, and torsional forces on the contact point of an ECG electrode, especially over long recording times, and an inflexibly fastened ECG electrode will be prone to becoming dislodged. Moreover, dislodgment may occur unbeknownst to the patient, making the ECG recordings worthless. Further, some patients may have skin that is susceptible to itching or irritation, and the wearing of ECG electrodes can aggravate such skin conditions. Thus, a patient may want or need to periodically remove or replace ECG electrodes during a long-term ECG monitoring period, whether to replace a dislodged electrode, reestablish better adhesion, alleviate itching or irritation, allow for cleansing of the skin, allow for showering and exercise, or for other purpose. Such replacement or slight alteration in electrode location actually facilitates the goal of recording the ECG signal for long periods of time.

Conventionally, multi-week or multi-month monitoring can be performed by implantable ECG monitors, such as the Reveal LINQ insertable cardiac monitor, manufactured by Medtronic, Inc., Minneapolis, MN. This monitor can detect and record paroxysmal or asymptomatic arrhythmias for up to three years. However, like all forms of implantable medical device (IMD), use of this monitor requires invasive surgical implantation, which significantly increases costs; requires ongoing follow up by a physician throughout the period of implantation; requires specialized equipment to retrieve monitoring data; and carries complications attendant to all surgery, including risks of infection, injury or death.

Holter monitors are widely used for extended ECG monitoring. Typically, they are often used for only 24-48 hours. A typical Holter monitor is a wearable and portable version of an ECG that include cables for each electrode placed on the skin and a separate battery-powered ECG recorder. The leads are placed in the anterior thoracic region in a manner similar to what is done with an in-clinic standard ECG machine using electrode locations that are not specifically intended for optimal P-wave capture. The duration of monitoring depends on the sensing and storage capabilities of the monitor. A "looping" Holter (or event) monitor can operate for a longer period of time by overwriting older ECG tracings, thence "recycling" storage in favor of extended operation, yet at the risk of losing event data. Although capable of extended ECG monitoring, Holter monitors are cumbersome, expensive and typically only available by medical prescription, which limits their usability. Further, the skill required to properly place the electrodes on the patient's chest precludes a patient from replacing or removing the sensing leads and usually involves moving the patient from the physician office to a specialized center within the hospital or clinic.

U.S. Pat. No. 8,460,189, to Libbus et al. ("Libbus") discloses an adherent wearable cardiac monitor that includes at least two measurement electrodes and an accelerometer. The device includes a reusable electronics module and a disposable adherent patch that includes the electrodes. ECG monitoring can be conducted using multiple disposable patches adhered to different locations on the patient's body. The device includes a processor configured to control collection and transmission of data from ECG circuitry, including generating and processing of ECG signals and data

acquired from two or more electrodes. The ECG circuitry can be coupled to the electrodes in many ways to define an ECG vector, and the orientation of the ECG vector can be determined in response to the polarity of the measurement electrodes and orientation of the electrode measurement axis. The accelerometer can be used to determine the orientation of the measurement electrodes in each of the locations. The ECG signals measured at different locations can be rotated based on the accelerometer data to modify amplitude and direction of the ECG features to approximate a standard ECG vector. The signals recorded at different locations can be combined by summing a scaled version of each signal. Libbus further discloses that inner ECG electrodes may be positioned near outer electrodes to increase the voltage of measured ECG signals. However, Libbus treats ECG signal acquisition as the measurement of a simple aggregate directional data signal without differentiating between the distinct kinds of cardiac electrical activities presented with an ECG waveform, particularly atrial (P-wave) activity.

The ZIO XT Patch and ZIO Event Card devices, manufactured by iRhythm Tech., Inc., San Francisco, CA, are wearable monitoring devices that are typically worn on the upper left pectoral region to respectively provide continuous and looping ECG recording. The location is used to simulate surgically implanted monitors, but without specifically enhancing P-wave capture. Both of these devices are prescription-only and for single patient use. The ZIO XT Patch device is limited to a 14-day period, while the electrodes only of the ZIO Event Card device can be worn for up to 30 days. The ZIO XT Patch device combines both electronic recordation components and physical electrodes into a unitary assembly that adheres to the patient's skin. The ZIO XT Patch device uses adhesive sufficiently strong to support the weight of both the monitor and the electrodes over an extended period and to resist disadherence from the patient's body, albeit at the cost of disallowing removal or relocation during the monitoring period. The ZIO Event Card device is a form of downsized Holter monitor with a recorder component that must be removed temporarily during baths or other activities that could damage the non-waterproof electronics. Both devices represent compromises between length of wear and quality of ECG monitoring, especially with respect to ease of long term use, female-friendly fit, and quality of cardiac electrical potential signals, especially atrial (P-wave) signals.

Therefore, a need remains for a low cost extended wear continuously recording ECG monitor attuned to capturing low amplitude cardiac action potential propagation for arrhythmia diagnosis, particularly atrial activation P-waves, and practicably capable of being worn for a long period of time, especially in patient's whose breast anatomy or size can interfere with signal quality in both women and men.

SUMMARY

Physiological monitoring can be provided through a lightweight wearable monitor that includes two components, a flexible extended wear electrode patch and a reusable monitor recorder that removably snaps into a receptacle on the electrode patch. The wearable monitor sits centrally (in the midline) on the patient's chest along the sternum oriented top-to-bottom. The ECG electrodes on the electrode patch are tailored to be positioned axially along the midline of the sternum for capturing action potential propagation in an orientation that corresponds to the aVF lead used in a conventional 12-lead ECG that is used to sense positive or

upright P-waves. The placement of the wearable monitor in a location at the sternal midline (or immediately to either side of the sternum), with its unique narrow "hourglass"-like shape, significantly improves the ability of the wearable monitor to cutaneously sense cardiac electrical potential signals, particularly the P-wave (or atrial activity) and, to a lesser extent, the QRS interval signals indicating ventricular activity in the ECG waveforms.

Moreover, the electrocardiography monitor offers superior patient comfort, convenience and user-friendliness. The electrode patch is specifically designed for ease of use by a patient (or caregiver); assistance by professional medical personnel is not required. The patient is free to replace the electrode patch at any time and need not wait for a doctor's appointment to have a new electrode patch placed. Patients can easily be taught to find the familiar physical landmarks on the body necessary for proper placement of the electrode patch. Empowering patients with the knowledge to place the electrode patch in the right place ensures that the ECG electrodes will be correctly positioned on the skin, no matter the number of times that the electrode patch is replaced. In addition, the monitor recorder operates automatically and the patient only need snap the monitor recorder into place on the electrode patch to initiate ECG monitoring. Thus, the synergistic combination of the electrode patch and monitor recorder makes the use of the electrocardiography monitor a reliable and virtually foolproof way to monitor a patient's ECG and physiology for an extended, or even open-ended, period of time.

In one embodiment, a moisture-resistant electrocardiography monitor is provided. The monitor includes an electrocardiography monitor recorder and an extended wear electrode patch. The electrocardiography monitor recorder includes a wearable housing molded out of one or more materials and sealed against moisture; a plurality of electrical contacts protruding from the wearable housing; a seal coupling positioned on the wearable housing and surrounding the electrical contacts; and electronic circuitry provided within the wearable housing. The electronic circuitry includes an electrocardiographic front end circuit under a control of a micro-controller and adapted to sense cardiac electrical potential differentials through electrocardiographic electrodes via some of the electrical contacts, which are provided to the micro-controller as an analog signal; the micro-controller configured to sample the analog signal; and a memory electrically interfaced with the micro-controller and operable to store the samples. The extended wear electrode patch includes a flexible backing including a plurality of adhesive contact surfaces; the electrocardiographic electrodes, each included on one of the adhesive contact surfaces; a receptacle affixed to a non-contacting surface of the flexible backing into which the wearable housing can be removable secured, the receptacle including a compartment within which a component interfaced to the electronic circuitry is positioned via some of the electrical contacts; a plurality of electrical pads positioned on the receptacle, each of the pads configured to interface with one of the electrical contacts when the wearable housing is secured within the receptacle; and a moisture-resistant seal formed on the receptacle and surrounding the electrical pads, wherein the moisture-resistant seal mates the seal coupling when the wearable housing is secured within the receptacle.

In a further embodiment, a moisture-resistant patient-interfacing electrocardiography monitor is provided. The monitor includes an electrocardiography monitor recorder and an extended wear electrode patch. The electrocardiography monitor recorder includes a wearable housing molded out of one or more materials and sealed against moisture; a waterproof patient-operable tactile feedback button positioned on an outside of the wearable housing; a plurality of electrical contacts protruding the wearable housing; a seal coupling positioned on the wearable housing and surrounding the electrical contacts; and electronic circuitry provided within the wearable housing. The electronic circuitry includes an electrocardiographic front end circuit under a control of a micro-controller and adapted to sense cardiac electrical potential differentials through electrocardiographic electrodes via some of the electrical contacts, which are provided to the micro-controller as an analog signal; the micro-controller configured to sample the analog signal; and a memory electrically interfaced with the micro-controller and operable to store the samples. The extended wear electrode patch includes: a flexible backing including a plurality of adhesive contact surfaces; the electrocardiographic electrodes, each included on one of the adhesive contact surfaces; a receptacle affixed to a non-contacting surface of the flexible backing into which the wearable housing can be removable secured, the receptacle including a compartment within which a battery, wherein the electronic circuitry is powered by the battery via at least some of the electrical contacts; a plurality of electrical pads positioned on the receptacle, each of the pads configured to interface with one of the electrical contacts when the wearable housing is secured within the receptacle; and a moisture-resistant seal formed on the receptacle and surrounding the electrical pads, wherein the moisture-resistant seal mates the seal coupling when the wearable housing is secured within the receptacle.

The monitoring patch is especially suited to the female anatomy, although also easily used over the male sternum. The narrow longitudinal midsection can fit nicely within the inter-mammary cleft of the breasts without inducing discomfort, whereas conventional patch electrodes are wide and, if adhered between the breasts, would cause chafing, irritation, discomfort, and annoyance, leading to low patient compliance.

In addition, the foregoing aspects enhance comfort in women (and certain men), but not irritation of the breasts, by placing the monitoring patch in the best location possible for optimizing the recording of cardiac signals from the atrium, particularly P-waves, which is another feature critical to proper arrhythmia and cardiac rhythm disorder diagnoses.

Still other embodiments will become readily apparent to those skilled in the art from the following detailed description, wherein are described embodiments by way of illustrating the best mode contemplated. As will be realized, other and different embodiments are possible and the embodiments' several details are capable of modifications in various obvious respects, all without departing from their spirit and the scope. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not as restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1** and **2** are diagrams showing, by way of examples, an extended wear electrocardiography monitor, including an extended wear electrode patch, in accordance with one embodiment, respectively fitted to the sternal region of a female patient and a male patient.

FIG. **3** is a front anatomical view showing, by way of illustration, the locations of the heart and lungs within the rib cage of an adult human.

FIG. **4** is a perspective view showing an extended wear electrode patch in accordance with one embodiment with a monitor recorder inserted.

FIG. **5** is a perspective view showing the monitor recorder of FIG. **4**.

FIG. **6** is a perspective view showing the extended wear electrode patch of FIG. **4** without a monitor recorder inserted.

FIG. **7** is a bottom plan view of the monitor recorder of FIG. **4**.

FIG. **8** is a top view showing the flexible circuit of the extended wear electrode patch of FIG. **4**.

FIG. **9** is a functional block diagram showing the component architecture of the circuitry of the monitor recorder of FIG. **4**.

FIG. **10** is a functional block diagram showing the circuitry of the extended wear electrode patch of FIG. **4**.

FIG. **11** is a schematic diagram showing the ECG front end circuit of the circuitry of the monitor recorder of FIG. **9**.

FIG. **12** is a flow diagram showing a monitor recorder-implemented method for monitoring ECG data for use in the monitor recorder of FIG. **4**.

FIG. **13** is a graph showing, by way of example, a typical ECG waveform.

FIG. **14** is a functional block diagram showing the signal processing functionality of the microcontroller.

FIG. **15** is a functional block diagram showing the operations performed by the download station.

FIGS. **16**A-C are functional block diagrams respectively showing practical uses of the extended wear electrocardiography monitors of FIGS. **1** and **2**.

FIG. **17** is a perspective view of an extended wear electrode patch with a flexile wire electrode assembly in accordance with a still further embodiment.

FIG. **18** is perspective view of the flexile wire electrode assembly from FIG. **17**, with a layer of insulating material shielding a bare distal wire around the midsection of the flexible backing.

FIG. **19** is a bottom view of the flexile wire electrode assembly as shown in FIG. **17**.

FIG. **20** is a bottom view of a flexile wire electrode assembly in accordance with a still yet further embodiment.

FIG. **21** is a perspective view showing the longitudinal midsection of the flexible backing of the electrode assembly from FIG. **17**.

DETAILED DESCRIPTION

ECG and physiological monitoring can be provided through a wearable ambulatory monitor that includes two components, a flexible extended wear electrode patch and a removable reusable (or single use) monitor recorder. Both the electrode patch and the monitor recorder are optimized to capture electrical signals from the propagation of low amplitude, relatively low frequency content cardiac action potentials, particularly the P-waves generated during atrial activation. FIGS. **1** and **2** are diagrams showing, by way of examples, an extended wear electrocardiography monitor **12**, including a monitor recorder **14**, in accordance with one embodiment, respectively fitted to the sternal region of a female patient **10** and a male patient **11**. The wearable monitor **12** sits centrally, positioned axially along the sternal midline **16**, on the patient's chest along the sternum **13** and oriented top-to-bottom with the monitor recorder **14** preferably situated towards the patient's head. In a further embodiment, the orientation of the wearable monitor **12** can be corrected post-monitoring, as further described infra, for instance, if the wearable monitor **12** is inadvertently fitted upside down.

The electrode patch **15** is shaped to fit comfortably and conformal to the contours of the patient's chest approximately centered on the sternal midline **16** (or immediately to either side of the sternum **13**). The distal end of the electrode patch **15**, under which a lower or inferior pole (ECG electrode) is adhered, extends towards the Xiphoid process and lower sternum and, depending upon the patient's build, may straddle the region over the Xiphoid process and lower sternum. The proximal end of the electrode patch **15**, located under the monitor recorder **14**, under which an upper or superior pole (ECG electrode) is adhered, is below the manubrium and, depending upon patient's build, may straddle the region over the manubrium.

During ECG monitoring, the amplitude and strength of action potentials sensed on the body's surface are affected to varying degrees by cardiac, cellular, extracellular, vector of current flow, and physical factors, like obesity, dermatitis, large breasts, and high impedance skin, as can occur in dark-skinned individuals. Sensing along the sternal midline **16** (or immediately to either side of the sternum **13**) significantly improves the ability of the wearable monitor **12** to cutaneously sense cardiac electric signals, particularly the P-wave (or atrial activity) and, to a lesser extent, the QRS interval signals in the ECG waveforms that indicate ventricular activity by countering some of the effects of these factors.

The ability to sense low amplitude, low frequency content body surface potentials is directly related to the location of ECG electrodes on the skin's surface and the ability of the sensing circuitry to capture these electrical signals. FIG. **3** is a front anatomical view showing, by way of illustration, the locations of the heart **4** and lungs **5** within the rib cage of an adult human. Depending upon their placement locations on the chest, ECG electrodes may be separated from activation regions within the heart **4** by differing combinations of internal tissues and body structures, including heart muscle, intracardiac blood, the pericardium, intrathoracic blood and fluids, the lungs **5**, skeletal muscle, bone structure, subcutaneous fat, and the skin, plus any contaminants present between the skin's surface and electrode signal pickups. The degree of amplitude degradation of cardiac transmembrane potentials increases with the number of tissue boundaries between the heart **4** and the skin's surface that are encountered. The cardiac electrical field is degraded each time the transmembrane potentials encounter a physical boundary separating adjoining tissues due to differences in the respective tissues' electrical resistances. In addition, other non-spatial factors, such as pericardial effusion, emphysema or fluid accumulation in the lungs, as further explained infra, can further degrade body surface potentials.

Internal tissues and body structures can adversely affect the current strength and signal fidelity of all body surface potentials, yet low amplitude cardiac action potentials, particularly the P-wave with a normative amplitude of less than 0.25 microvolts (mV) and a normative duration of less than 120 milliseconds (ms), are most apt to be negatively impacted. The atria **6** are generally located posteriorly within the thoracic cavity (with the exception of the anterior right atrium and right atrial appendage), and, physically, the left atrium constitutes the portion of the heart **4** furthest away from the surface of the skin on the chest. Conversely, the ventricles **7**, which generate larger amplitude signals, generally are located anteriorly with the anterior right ventricle and most of the left ventricle situated relatively close

to the skin surface on the chest, which contributes to the relatively stronger amplitudes of ventricular waveforms. Thus, the quality of P-waves (and other already-low amplitude action potential signals) is more susceptible to weakening from intervening tissues and structures than the waveforms associated with ventricular activation.

The importance of the positioning of ECG electrodes along the sternal midline **15** has largely been overlooked by conventional approaches to ECG monitoring, in part due to the inability of their sensing circuitry to reliably detect low amplitude, low frequency content electrical signals, particularly in P-waves. In turn, that inability to keenly sense P-waves has motivated ECG electrode placement in other non-sternal midline thoracic locations, where the QRSTU components that represent ventricular electrical activity are more readily detectable by their sensing circuitry than P-waves. In addition, ECG electrode placement along the sternal midline **15** presents major patient wearability challenges, such as fitting a monitoring ensemble within the narrow confines of the inter-mammary cleft between the breasts, that to large extent drive physical packaging concerns, which can be incompatible with ECG monitors intended for placement, say, in the upper pectoral region or other non-sternal midline thoracic locations. In contrast, the wearable monitor **12** uses an electrode patch **15** that is specifically intended for extended wear placement in a location at the sternal midline **16** (or immediately to either side of the sternum **13**). When combined with a monitor recorder **14** that uses sensing circuitry optimized to preserve the characteristics of low amplitude cardiac action potentials, especially those signals from the atria, as further described infra with reference to FIG. **11**, the electrode patch **15** helps to significantly improve atrial activation (P-wave) sensing through placement in a body location that robustly minimizes the effects of tissue and body structure.

Referring back to FIGS. **1** and **2**, the placement of the wearable monitor **12** in the region of the sternal midline **13** puts the ECG electrodes of the electrode patch **15** in locations better adapted to sensing and recording low amplitude cardiac action potentials during atrial propagation (P-wave signals) than placement in other locations, such as the upper left pectoral region, as commonly seen in most conventional ambulatory ECG monitors. The sternum **13** overlies the right atrium of the heart **4**. As a result, action potential signals have to travel through fewer layers of tissue and structure to reach the ECG electrodes of the electrode patch **15** on the body's surface along the sternal midline **13** when compared to other monitoring locations, a distinction that is of critical importance when capturing low frequency content electrical signals, such as P-waves.

Moreover, cardiac action potential propagation travels simultaneously along a north-to-south and right-to-left vector, beginning high in the right atrium and ultimately ending in the posterior and lateral region of the left ventricle. Cardiac depolarization originates high in the right atrium in the SA node before concurrently spreading leftward towards the left atrium and inferiorly towards the AV node. The ECG electrodes of the electrode patch **15** are placed with the upper or superior pole (ECG electrode) along the sternal midline **13** in the region of the manubrium and the lower or inferior pole (ECG electrode) along the sternal midline **13** in the region of the Xiphoid process **9** and lower sternum. The ECG electrodes are placed primarily in a north-to-south orientation along the sternum **13** that corresponds to the north-to-south waveform vector exhibited during atrial activation. This orientation corresponds to the aVF lead used in a conventional 12-lead ECG that is used to sense positive or upright P-waves.

Furthermore, the thoracic region underlying the sternum **13** along the midline **16** between the manubrium **8** and Xiphoid process **9** is relatively free of lung tissue, musculature, and other internal body structures that could occlude the electrical signal path between the heart **4**, particularly the atria, and ECG electrodes placed on the surface of the skin. Fewer obstructions means that cardiac electrical potentials encounter fewer boundaries between different tissues. As a result, when compared to other thoracic ECG sensing locations, the cardiac electrical field is less altered when sensed dermally along the sternal midline **13**. As well, the proximity of the sternal midline **16** to the ventricles **7** facilitates sensing of right ventricular activity and provides superior recordation of the QRS interval, again, in part due to the relatively clear electrical path between the heart **4** and the skin surface.

Finally, non-spatial factors can affect transmembrane action potential shape and conductivity. For instance, myocardial ischemia, an acute cardiac condition, can cause a transient increase in blood perfusion in the lungs **5**. The perfused blood can significantly increase electrical resistance across the lungs **5** and therefore degrade transmission of the cardiac electrical field to the skin's surface. However, the placement of the wearable monitor **12** along the sternal midline **16** in the inter-mammary cleft between the breasts is relatively resilient to the adverse effects to cardiac action potential degradation caused by ischemic conditions as the body surface potentials from a location relatively clear of underlying lung tissue and fat help compensate for the loss of signal amplitude and content. The monitor recorder **14** is thus able to record the P-wave morphology that may be compromised by myocardial ischemia and therefore make diagnosis of the specific arrhythmias that can be associated with myocardial ischemia more difficult.

During use, the electrode patch **15** is first adhered to the skin along the sternal midline **16** (or immediately to either side of the sternum **13**). A monitor recorder **14** is then snapped into place on the electrode patch **15** using an electro mechanical docking interface to initiate ECG monitoring. FIG. **4** is a perspective view showing an extended wear electrode patch **15** in accordance with one embodiment with a monitor recorder **14** inserted. The body of the electrode patch **15** is preferably constructed using a flexible backing **20** formed as an elongated strip **21** of wrap knit or similar stretchable material about 145 mm long and 32 mm at the widest point with a narrow longitudinal mid-section **23** evenly tapering inward from both sides. A pair of cut-outs **22** between the distal and proximal ends of the electrode patch **15** create a narrow longitudinal midsection **23** or "isthmus" and defines an elongated "hourglass"-like shape, when viewed from above, such as described in commonly-assigned U.S. Design Patent No. D744,659, issued Dec. 1, 2015, the disclosure of which is incorporated by reference. The upper part of the "hourglass" is sized to allow an electrically non-conductive receptacle **25**, sits on top of the outward-facing surface of the electrode patch **15**, to be affixed to the electrode patch **15** with an ECG electrode placed underneath on the patient-facing underside, or contact, surface of the electrode patch **15**; the upper part of the "hourglass" has a longer and wider profile (but still rounded and tapered to fit comfortably between the breasts) than the lower part of the "hourglass," which is sized primarily to allow just the placement of an ECG electrode of appropriate

shape and surface area to record the P-wave and the QRS signals sufficiently given the inter-electrode spacing.

The electrode patch **15** incorporates features that significantly improve wearability, performance, and patient comfort throughout an extended monitoring period. The entire electrode patch **15** is lightweight in construction, which allows the patch to be resilient to disadhesing or falling off and, critically, to avoid creating distracting discomfort to the patient, even when the patient is asleep. In contrast, the weight of a heavy ECG monitor impedes patient mobility and will cause the monitor to constantly tug downwards and press on the patient's body that can generate skin inflammation with frequent adjustments by the patient needed to maintain comfort.

During every day wear, the electrode patch **15** is subjected to pushing, pulling, and torsional movements, including compressional and torsional forces when the patient bends forward, or tensile and torsional forces when the patient leans backwards. To counter these stress forces, the electrode patch **15** incorporates crimp and strain reliefs, such as described in commonly-assigned U.S. Pat. No. 9,545,204, issued Jan. 17, 2017, the disclosure of which is incorporated by reference. In addition, the cut-outs **22** and longitudinal midsection **23** help minimize interference with and discomfort to breast tissue, particularly in women (and gynecomastic men). The cut-outs **22** and longitudinal midsection **23** further allow better conformity of the electrode patch **15** to sternal bowing and to the narrow isthmus of flat skin that can occur along the bottom of the inter-mammary cleft between the breasts, especially in buxom women. The cut-outs **22** and narrow and flexible longitudinal midsection **23** help the electrode patch **15** fit nicely between a pair of female breasts in the inter-mammary cleft. In one embodiment, the cut-outs **22** can be graduated to form the longitudinal midsection **23** as a narrow in-between stem or isthmus portion about 7 mm wide. In a still further embodiment, tabs **24** can respectively extend an additional 8 mm to 12 mm beyond the distal and proximal ends of the flexible backing **20** to facilitate with adhering the electrode patch **15** to or removing the electrode patch **15** from the sternum **13**. These tabs preferably lack adhesive on the underside, or contact, surface of the electrode patch **15**. Still other shapes, cut-outs and conformities to the electrode patch **15** are possible.

The monitor recorder **14** removably and reusably snaps into an electrically non-conductive receptacle **25** during use. The monitor recorder **14** contains electronic circuitry for recording and storing the patient's electrocardiography as sensed via a pair of ECG electrodes provided on the electrode patch **15**, as further described infra beginning with reference to FIG. **9**. The non-conductive receptacle **25** is provided on the top surface of the flexible backing **20** with a retention catch **26** and tension clip **27** molded into the non-conductive receptacle **25** to conformably receive and securely hold the monitor recorder **14** in place.

The monitor recorder **14** includes a sealed housing that snaps into place in the non-conductive receptacle **25**. FIG. **5** is a perspective view showing the monitor recorder **14** of FIG. **4**. The sealed housing **50** of the monitor recorder **14** intentionally has a rounded isosceles trapezoidal-like shape **52**, when viewed from above, such as described in commonly-assigned U.S. Design Patent No. D717,955, issued Nov. 18, 2014, the disclosure of which is incorporated by reference. The edges **51** along the top and bottom surfaces are rounded for patient comfort. The sealed housing **50** is approximately 47 mm long, 23 mm wide at the widest point, and 7 mm high, excluding a patient-operable tactile-feedback button **55**. The sealed housing **50** can be molded out of polycarbonate, ABS, or an alloy of those two materials. The button **55** is waterproof and the button's top outer surface is molded silicon rubber or similar soft pliable material. A retention detent **53** and tension detent **54** are molded along the edges of the top surface of the housing **50** to respectively engage the retention catch **26** and the tension clip **27** molded into non-conductive receptacle **25**. Other shapes, features, and conformities of the sealed housing **50** are possible.

The electrode patch **15** is intended to be disposable, while the monitor recorder **14** is designed for reuse and can be transferred to successive electrode patches **15** to ensure continuity of monitoring, if so desired. The monitor recorder **14** can be used only once, but single use effectively wastes the synergistic benefits provided by the combination of the disposable electrode patch and reusable monitor recorder, as further explained infra with reference to FIGS. **16**A-C. The placement of the wearable monitor **12** in a location at the sternal midline **16** (or immediately to either side of the sternum **13**) benefits long-term extended wear by removing the requirement that ECG electrodes be continually placed in the same spots on the skin throughout the monitoring period. Instead, the patient is free to place an electrode patch **15** anywhere within the general region of the sternum **13**.

As a result, at any point during ECG monitoring, the patient's skin is able to recover from the wearing of an electrode patch **15**, which increases patient comfort and satisfaction, while the monitor recorder **14** ensures ECG monitoring continuity with minimal effort. A monitor recorder **14** is merely unsnapped from a worn out electrode patch **15**, the worn out electrode patch **15** is removed from the skin, a new electrode patch **15** is adhered to the skin, possibly in a new spot immediately adjacent to the earlier location, and the same monitor recorder **14** is snapped into the new electrode patch **15** to reinitiate and continue the ECG monitoring.

During use, the electrode patch **15** is first adhered to the skin in the sternal region. FIG. **6** is a perspective view showing the extended wear electrode patch **15** of FIG. **4** without a monitor recorder **14** inserted. A flexible circuit **32** is adhered to each end of the flexible backing **20**. A distal circuit trace **33** from the distal end **30** of the flexible backing **20** and a proximal circuit trace (not shown) from the proximal end **31** of the flexible backing **20** electrically couple ECG electrodes (not shown) with a pair of electrical pads **34**. In a further embodiment, the distal and proximal circuit traces are replaced with interlaced or sewn-in flexible wires, as further described infra beginning with reference to FIG. **17**. The electrical pads **34** are provided within a moisture-resistant seal **35** formed on the bottom surface of the non-conductive receptacle **25**. When the monitor recorder **14** is securely received into the non-conductive receptacle **25**, that is, snapped into place, the electrical pads **34** interface to electrical contacts (not shown) protruding from the bottom surface of the monitor recorder **14**. The moisture-resistant seal **35** enables the monitor recorder **14** to be worn at all times, even during showering or other activities that could expose the monitor recorder **14** to moisture or adverse conditions.

In addition, a battery compartment **36** is formed on the bottom surface of the non-conductive receptacle **25**. A pair of battery leads (not shown) from the battery compartment **36** to another pair of the electrical pads **34** electrically interface the battery to the monitor recorder **14**. The battery contained within the battery compartment **35** is a direct current (DC) power cell and can be replaceable, rechargeable or disposable.

The monitor recorder **14** draws power externally from the battery provided in the non-conductive receptacle **25**, thereby uniquely obviating the need for the monitor recorder **14** to carry a dedicated power source. FIG. **7** is a bottom plan view of the monitor recorder **14** of FIG. **4**. A cavity **58** is formed on the bottom surface of the sealed housing **50** to accommodate the upward projection of the battery compartment **36** from the bottom surface of the non-conductive receptacle **25**, when the monitor recorder **14** is secured in place on the non-conductive receptacle **25**. A set of electrical contacts **56** protrude from the bottom surface of the sealed housing **50** and are arranged in alignment with the electrical pads **34** provided on the bottom surface of the non-conductive receptacle **25** to establish electrical connections between the electrode patch **15** and the monitor recorder **14**. In addition, a seal coupling **57** circumferentially surrounds the set of electrical contacts **56** and securely mates with the moisture-resistant seal **35** formed on the bottom surface of the non-conductive receptacle **25**. The battery contained within the battery compartment **36** can be replaceable, rechargeable or disposable. In a further embodiment, the ECG sensing circuitry of the monitor recorder **14** can be supplemented with additional sensors, including an SpO_2 sensor, a blood pressure sensor, a temperature sensor, respiratory rate sensor, a glucose sensor, an air flow sensor, and a volumetric pressure sensor, which can be incorporated directly into the monitor recorder **14** or onto the non-conductive receptacle **25**.

The placement of the flexible backing **20** on the sternal midline **16** (or immediately to either side of the sternum **13**) also helps to minimize the side-to-side movement of the wearable monitor **12** in the left- and right-handed directions during wear. However, the wearable monitor **12** is still susceptible to pushing, pulling, and torqueing movements, including compressional and torsional forces when the patient bends forward, and tensile and torsional forces when the patient leans backwards or twists. To counter the dislodgment of the flexible backing **20** due to compressional and torsional forces, a layer of non-irritating adhesive, such as hydrocolloid, is provided at least partially on the underside, or contact, surface of the flexible backing **20**, but only on the distal end **30** and the proximal end **31**. As a result, the underside, or contact surface of the longitudinal midsection **23** does not have an adhesive layer and remains free to move relative to the skin. Thus, the longitudinal midsection **23** forms a crimp relief that respectively facilitates compression and twisting of the flexible backing **20** in response to compressional and torsional forces. Other forms of flexible backing crimp reliefs are possible.

Unlike the flexible backing **20**, the flexible circuit **32** is only able to bend and cannot stretch in a planar direction. The flexible circuit **32** can be provided either above or below the flexible backing **20**. FIG. **8** is a top view showing the flexible circuit **32** of the extended wear electrode patch **15** of FIG. **4** when mounted above the flexible backing **20**. A distal ECG electrode **38** and proximal ECG electrode **39** are respectively coupled to the distal and proximal ends of the flexible circuit **32** to serve as electrode signal pickups. The flexible circuit **32** preferably does not extend to the outside edges of the flexible backing **20**, thereby avoiding gouging or discomforting the patient's skin during extended wear, such as when sleeping on the side. During wear, the ECG electrodes **38**, **39** must remain in continual contact with the skin. A strain relief **40** is defined in the flexible circuit **32** at a location that is partially underneath the battery compartment **36** when the flexible circuit **32** is affixed to the flexible backing **20**. The strain relief **40** is laterally extendable to counter dislodgment of the ECG electrodes **38**, **39** due to bending, tensile and torsional forces. A pair of strain relief cutouts **41** partially extend transversely from each opposite side of the flexible circuit **32** and continue longitudinally towards each other to define in 'S'-shaped pattern, when viewed from above. The strain relief respectively facilitates longitudinal extension and twisting of the flexible circuit **32** in response to tensile and torsional forces. Other forms of circuit board strain relief are possible.

ECG monitoring and other functions performed by the monitor recorder **14** are provided through a micro controlled architecture. FIG. **9** is a functional block diagram showing the component architecture of the circuitry **60** of the monitor recorder **14** of FIG. **4**. The circuitry **60** is externally powered through a battery provided in the non-conductive receptacle **25** (shown in FIG. **6**). Both power and raw ECG signals, which originate in the pair of ECG electrodes **38**, **39** (shown in FIG. **8**) on the distal and proximal ends of the electrode patch **15**, are received through an external connector **65** that mates with a corresponding physical connector on the electrode patch **15**. The external connector **65** includes the set of electrical contacts **56** that protrude from the bottom surface of the sealed housing **50** and which physically and electrically interface with the set of pads **34** provided on the bottom surface of the non-conductive receptacle **25**. The external connector includes electrical contacts **56** for data download, microcontroller communications, power, analog inputs, and a peripheral expansion port. The arrangement of the pins on the electrical connector **65** of the monitor recorder **14** and the device into which the monitor recorder **14** is attached, whether an electrode patch **15** or download station (not shown), follow the same electrical pin assignment convention to facilitate interoperability. The external connector **65** also serves as a physical interface to a download station that permits the retrieval of stored ECG monitoring data, communication with the monitor recorder **14**, and performance of other functions. The download station is further described infra with reference to FIG. **15**.

Operation of the circuitry **60** of the monitor recorder **14** is managed by a microcontroller **61**, such as the EFM32 Tiny Gecko 32-bit microcontroller, manufactured by Silicon Laboratories Inc., Austin, TX. The microcontroller **61** has flexible energy management modes and includes a direct memory access controller and built-in analog-to-digital and digital-to-analog converters (ADC and DAC, respectively). The microcontroller **61** also includes a program memory unit containing internal flash memory that is readable and writeable. The internal flash memory can also be programmed externally. The microcontroller **61** operates under modular micro program control as specified in firmware stored in the internal flash memory. The functionality and firmware modules relating to signal processing by the microcontroller **61** are further described infra with reference to FIG. **14**. The microcontroller **61** draws power externally from the battery provided on the electrode patch **15** via a pair of the electrical contacts **56**. The microcontroller **61** connects to the ECG front end circuit **63** that measures raw cutaneous electrical signals using a driven reference that eliminates common mode noise, as further described infra with reference to FIG. **11**.

The circuitry **60** of the monitor recorder **14** also includes a flash memory **62**, which the microcontroller **61** uses for storing ECG monitoring data and other physiology and information. The flash memory **62** also draws power externally from the battery provided on the electrode patch **15** via a pair of the electrical contacts **56**. Data is stored in a serial flash memory circuit, which supports read, erase and pro-

gram operations over a communications bus. The flash memory **62** enables the microcontroller **61** to store digitized ECG data. The communications bus further enables the flash memory **62** to be directly accessed externally over the external connector **65** when the monitor recorder **14** is interfaced to a download station.

The microcontroller **61** includes functionality that enables the acquisition of samples of analog ECG signals, which are converted into a digital representation, as further described infra with reference to FIG. **14**. In one mode, the microcontroller **61** will acquire, sample, digitize, signal process, and store digitized ECG data into available storage locations in the flash memory **62** until all memory storage locations are filled, after which the digitized ECG data needs to be downloaded or erased to restore memory capacity. Data download or erasure can also occur before all storage locations are filled, which would free up memory space sooner, albeit at the cost of possibly interrupting monitoring while downloading or erasure is performed. In another mode, the microcontroller **61** can include a loop recorder feature that will overwrite the oldest stored data once all storage locations are filled, albeit at the cost of potentially losing the stored data that was overwritten, if not previously downloaded. Still other modes of data storage and capacity recovery are possible.

The circuitry **60** of the monitor recorder **14** further includes an actigraphy sensor **64** implemented as a 3-axis accelerometer. The accelerometer may be configured to generate interrupt signals to the microcontroller **61** by independent initial wake up and free fall events, as well as by device position. In addition, the actigraphy provided by the accelerometer can be used during post-monitoring analysis to correct the orientation of the monitor recorder **14** if, for instance, the monitor recorder **14** has been inadvertently installed upside down, that is, with the monitor recorder **14** oriented on the electrode patch **15** towards the patient's feet, as well as for other event occurrence analyses.

The microcontroller **61** includes an expansion port that also utilizes the communications bus. External devices, separately drawing power externally from the battery provided on the electrode patch **15** or other source, can interface to the microcontroller **61** over the expansion port in half duplex mode. For instance, an external physiology sensor can be provided as part of the circuitry **60** of the monitor recorder **14**, or can be provided on the electrode patch **15** with communication with the microcontroller **61** provided over one of the electrical contacts **56**. The physiology sensor can include an SpO_2 sensor, blood pressure sensor, temperature sensor, respiratory rate sensor, glucose sensor, airflow sensor, volumetric pressure sensing, or other types of sensor or telemetric input sources. In a further embodiment, a wireless interface for interfacing with other wearable (or implantable) physiology monitors, as well as data offload and programming, can be provided as part of the circuitry **60** of the monitor recorder **14**, or can be provided on the electrode patch **15** with communication with the microcontroller **61** provided over one of the electrical contacts **56**.

Finally, the circuitry **60** of the monitor recorder **14** includes patient-interfaceable components, including a tactile feedback button **66**, which a patient can press to mark events or to perform other functions, and a buzzer **67**, such as a speaker, magnetic resonator or piezoelectric buzzer. The buzzer **67** can be used by the microcontroller **61** to output feedback to a patient such as to confirm power up and initiation of ECG monitoring. Still other components as part of the circuitry **60** of the monitor recorder **14** are possible.

While the monitor recorder **14** operates under micro control, most of the electrical components of the electrode patch **15** operate passively. FIG. **10** is a functional block diagram showing the circuitry **70** of the extended wear electrode patch **15** of FIG. **4**. The circuitry **70** of the electrode patch **15** is electrically coupled with the circuitry **60** of the monitor recorder **14** through an external connector **74**. The external connector **74** is terminated through the set of pads **34** provided on the bottom of the non-conductive receptacle **25**, which electrically mate to corresponding electrical contacts **56** protruding from the bottom surface of the sealed housing **50** to electrically interface the monitor recorder **14** to the electrode patch **15**.

The circuitry **70** of the electrode patch **15** performs three primary functions. First, a battery **71** is provided in a battery compartment formed on the bottom surface of the non-conductive receptacle **25**. The battery **71** is electrically interfaced to the circuitry **60** of the monitor recorder **14** as a source of external power. The unique provisioning of the battery **71** on the electrode patch **15** provides several advantages. First, the locating of the battery **71** physically on the electrode patch **15** lowers the center of gravity of the overall wearable monitor **12** and thereby helps to minimize shear forces and the effects of movements of the patient and clothing. Moreover, the housing **50** of the monitor recorder **14** is sealed against moisture and providing power externally avoids having to either periodically open the housing **50** for the battery replacement, which also creates the potential for moisture intrusion and human error, or to recharge the battery, which can potentially take the monitor recorder **14** off line for hours at a time. In addition, the electrode patch **15** is intended to be disposable, while the monitor recorder **14** is a reusable component. Each time that the electrode patch **15** is replaced, a fresh battery is provided for the use of the monitor recorder **14**, which enhances ECG monitoring performance quality and duration of use. Also, the architecture of the monitor recorder **14** is open, in that other physiology sensors or components can be added by virtue of the expansion port of the microcontroller **61**. Requiring those additional sensors or components to draw power from a source external to the monitor recorder **14** keeps power considerations independent of the monitor recorder **14**. This approach also enables a battery of higher capacity to be introduced when needed to support the additional sensors or components without effecting the monitor recorders circuitry **60**.

Second, the pair of ECG electrodes **38**, **39** respectively provided on the distal and proximal ends of the flexible circuit **32** are electrically coupled to the set of pads **34** provided on the bottom of the non-conductive receptacle **25** by way of their respective circuit traces **33**, **37**. The signal ECG electrode **39** includes a protection circuit **72**, which is an inline resistor that protects the patient from excessive leakage current should the front end circuit fail.

Last, in a further embodiment, the circuitry **70** of the electrode patch **15** includes a cryptographic circuit **73** to authenticate an electrode patch **15** for use with a monitor recorder **14**. The cryptographic circuit **73** includes a device capable of secure authentication and validation. The cryptographic device **73** ensures that only genuine, non-expired, safe, and authenticated electrode patches **15** are permitted to provide monitoring data to a monitor recorder **14** and for a specific patient.

The ECG front end circuit **63** measures raw cutaneous electrical signals using a driven reference that effectively reduces common mode noise, power supply noise and system noise, which is critical to preserving the character-

istics of low amplitude cardiac action potentials, especially those signals from the atria. FIG. **11** is a schematic diagram **80** showing the ECG front end circuit **63** of the circuitry **60** of the monitor recorder **14** of FIG. **9**. The ECG front end circuit **63** senses body surface potentials through a signal lead ("Si") and reference lead ("REF") that are respectively connected to the ECG electrodes of the electrode patch **15**. Power is provided to the ECG front end circuit **63** through a pair of DC power leads ("VCC" and "GND"). An analog ECG signal ("ECG") representative of the electrical activity of the patient's heart over time is output, which the micro controller **11** converts to digital representation and filters, as further described infra.

The ECG front end circuit **63** is organized into five stages, a passive input filter stage **81**, a unity gain voltage follower stage **82**, a passive high pass filtering stage **83**, a voltage amplification and active filtering stage **84**, and an anti-aliasing passive filter stage **85**, plus a reference generator. Each of these stages and the reference generator will now be described.

The passive input filter stage **81** includes the parasitic impedance of the ECG electrodes **38**, **39** (shown in FIG. **8**), the protection resistor that is included as part of the protection circuit **72** of the ECG electrode **39** (shown in FIG. **10**), an AC coupling capacitor **87**, a termination resistor **88**, and filter capacitor **89**. This stage passively shifts the frequency response poles downward there is a high electrode impedance from the patient on the signal lead Si and reference lead REF, which reduces high frequency noise.

The unity gain voltage follower stage **82** provides a unity voltage gain that allows current amplification by an Operational Amplifier ("Op Amp") **90**. In this stage, the voltage stays the same as the input, but more current is available to feed additional stages. This configuration allows a very high input impedance, so as not to disrupt the body surface potentials or the filtering effect of the previous stage.

The passive high pass filtering stage **83** is a high pass filter that removes baseline wander and any offset generated from the previous stage. Adding an AC coupling capacitor **91** after the Op Amp **90** allows the use of lower cost components, while increasing signal fidelity.

The voltage amplification and active filtering stage **84** amplifies the voltage of the input signal through Op Amp **92**, while applying a low pass filter. The DC bias of the input signal is automatically centered in the highest performance input region of the Op Amp **92** because of the AC coupling capacitor **91**.

The anti-aliasing passive filter stage **85** provides an anti-aliasing low pass filter. When the microcontroller **61** acquires a sample of the analog input signal, a disruption in the signal occurs as a sample and hold capacitor that is internal to the microcontroller **61** is charged to supply signal for acquisition.

The reference generator in subcircuit **86** drives a driven reference containing power supply noise and system noise to the reference lead REF. A coupling capacitor **87** is included on the signal lead Si and a pair of resistors **93***a*, **93***b* inject system noise into the reference lead REF. The reference generator is connected directly to the patient, thereby avoiding the thermal noise of the protection resistor that is included as part of the protection circuit **72**.

In contrast, conventional ECG lead configurations try to balance signal and reference lead connections. The conventional approach suffers from the introduction of differential thermal noise, lower input common mode rejection, increased power supply noise, increased system noise, and differential voltages between the patient reference and the reference used on the device that can obscure, at times, extremely, low amplitude body surface potentials.

Here, the parasitic impedance of the ECG electrodes **38**, **39**, the protection resistor that is included as part of the protection circuit **72** and the coupling capacitor **87** allow the reference lead REF to be connected directly to the skin's surface without any further components. As a result, the differential thermal noise problem caused by pairing protection resistors to signal and reference leads, as used in conventional approaches, is avoided.

The monitor recorder **14** continuously monitors the patient's heart rate and physiology. FIG. **12** is a flow diagram showing a monitor recorder-implemented method **100** for monitoring ECG data for use in the monitor recorder **14** of FIG. **4**. Initially, upon being connected to the set of pads **34** provided with the non-conductive receptacle **25** when the monitor recorder **14** is snapped into place, the microcontroller **61** executes a power up sequence (step **101**). During the power up sequence, the voltage of the battery **71** is checked, the state of the flash memory **62** is confirmed, both in terms of operability check and available capacity, and microcontroller operation is diagnostically confirmed. In a further embodiment, an authentication procedure between the microcontroller **61** and the electrode patch **15** are also performed.

Following satisfactory completion of the power up sequence, an iterative processing loop (steps **102**-**110**) is continually executed by the microcontroller **61**. During each iteration (step **102**) of the processing loop, the ECG frontend **63** (shown in FIG. **9**) continually senses the cutaneous ECG electrical signals (step **103**) via the ECG electrodes **38**, **29** and is optimized to maintain the integrity of the P-wave. A sample of the ECG signal is read (step **104**) by the microcontroller **61** by sampling the analog ECG signal that is output by the ECG front end circuit **63**. FIG. **13** is a graph showing, by way of example, a typical ECG waveform **120**. The x-axis represents time in approximate units of tenths of a second. The y-axis represents cutaneous electrical signal strength in approximate units of millivolts. The P-wave **121** has a smooth, normally upward, that is, positive, waveform that indicates atrial depolarization. The QRS complex often begins with the downward deflection of a Q-wave **122**, followed by a larger upward deflection of an R-wave **123**, and terminated with a downward waveform of the S-wave **124**, collectively representative of ventricular depolarization. The T-wave **125** is normally a modest upward waveform, representative of ventricular depolarization, while the U-wave **126**, often not directly observable, indicates the recovery period of the Purkinje conduction fibers.

Sampling of the R-to-R interval enables heart rate information derivation. For instance, the R-to-R interval represents the ventricular rate and rhythm, while the P-to-P interval represents the atrial rate and rhythm. Importantly, the PR interval is indicative of atrioventricular (AV) conduction time and abnormalities in the PR interval can reveal underlying heart disorders, thus representing another reason why the P-wave quality achievable by the ambulatory electrocardiography monitoring patch optimized for capturing low amplitude cardiac action potential propagation described herein is medically unique and important. The long-term observation of these ECG indicia, as provided through extended wear of the wearable monitor **12**, provides valuable insights to the patient's cardiac function symptoms, and overall well-being.

Referring back to FIG. **12**, each sampled ECG signal, in quantized and digitized form, is processed by signal processing modules as specified in firmware (step **105**), as

described infra, and temporarily staged in a buffer (step **106**), pending compression preparatory to storage in the flash memory **62** (step **107**). Following compression, the compressed ECG digitized sample is again buffered (step **108**), then written to the flash memory **62** (step **109**) using the communications bus. Processing continues (step **110**), so long as the monitoring recorder **14** remains connected to the electrode patch **15** (and storage space remains available in the flash memory **62**), after which the processing loop is exited (step **110**) and execution terminates. Still other operations and steps are possible.

The microcontroller **61** operates under modular micro program control as specified in firmware, and the program control includes processing of the analog ECG signal output by the ECG front end circuit **63**. FIG. **14** is a functional block diagram showing the signal processing functionality **130** of the microcontroller **61**. The microcontroller **61** operates under modular micro program control as specified in firmware **132**. The firmware modules **132** include high and low pass filtering **133**, and compression **134**. Other modules are possible. The microcontroller **61** has a built-in ADC, although ADC functionality could also be provided in the firmware **132**.

The ECG front end circuit **63** first outputs an analog ECG signal, which the ADC **131** acquires, samples and converts into an uncompressed digital representation. The microcontroller **61** includes one or more firmware modules **133** that perform filtering. In one embodiment, three low pass filters and two high pass filters are used. Following filtering, the digital representation of the cardiac activation wave front amplitudes are compressed by a compression module **134** before being written out to storage **135**.

The download station executes a communications or offload program ("Offload") or similar program that interacts with the monitor recorder **14** via the external connector **65** to retrieve the stored ECG monitoring data. FIG. **15** is a functional block diagram showing the operations **140** performed by the download station. The download station could be a server, personal computer, tablet or handheld computer, smart mobile device, or purpose-built programmer designed specific to the task of interfacing with a monitor recorder **14**. Still other forms of download station are possible, including download stations connected through wireless interfacing using, for instance, a smart phone connected to the monitor recorder **14** through Bluetooth or Wi-Fi.

The download station is responsible for offloading stored ECG monitoring data from a monitor recorder **14** and includes an electro mechanical docking interface by which the monitor recorder **14** is connected at the external connector **65**. The download station operates under programmable control as specified in software **141**. The stored ECG monitoring data retrieved from storage **142** on a monitor recorder **14** is first decompressed by a decompression module **143**, which converts the stored ECG monitoring data back into an uncompressed digital representation more suited to signal processing than a compressed signal. The retrieved ECG monitoring data may be stored into local storage for archival purposes, either in original compressed form, or as uncompressed.

The download station can include an array of filtering modules. For instance, a set of phase distortion filtering tools **144** may be provided, where corresponding software filters can be provided for each filter implemented in the firmware executed by the microcontroller **61**. The digital signals are run through the software filters in a reverse direction to remove phase distortion. For instance, a 45 Hertz high pass filter in firmware may have a matching reverse 45 Hertz high pass filter in software. Most of the phase distortion is corrected, that is, canceled to eliminate noise at the set frequency, but data at other frequencies in the waveform remain unaltered. As well, bidirectional impulse infinite response (IIR) high pass filters and reverse direction (symmetric) IIR low pass filters can be provided. Data is run through these filters first in a forward direction, then in a reverse direction, which generates a square of the response and cancels out any phase distortion. This type of signal processing is particularly helpful with improving the display of the ST-segment by removing low frequency noise.

An automatic gain control (AGC) module **145** can also be provided to adjust the digital signals to a usable level based on peak or average signal level or other metric. AGC is particularly critical to single-lead ECG monitors, where physical factors, such as the tilt of the heart, can affect the electrical field generated. On three-lead Holter monitors, the leads are oriented in vertical, horizontal and diagonal directions. As a result, the horizontal and diagonal leads may be higher amplitude and ECG interpretation will be based on one or both of the higher amplitude leads. In contrast, the electrocardiography monitor **12** has only a single lead that is oriented in the vertical direction, so variations in amplitude will be wider than available with multi-lead monitors, which have alternate leads to fall back upon.

In addition, AGC may be necessary to maintain compatibility with existing ECG interpretation software, which is typically calibrated for multi-lead ECG monitors for viewing signals over a narrow range of amplitudes. Through the AGC module **145**, the gain of signals recorded by the monitor recorder **14** of the electrocardiography monitor **12** can be attenuated up (or down) to work with FDA-approved commercially available ECG interpretation.

AGC can be implemented in a fixed fashion that is uniformly applied to all signals in an ECG recording, adjusted as appropriate on a recording-by-recording basis. Typically, a fixed AGC value is calculated based on how an ECG recording is received to preserve the amplitude relationship between the signals. Alternatively, AGC can be varied dynamically throughout an ECG recording, where signals in different segments of an ECG recording are amplified up (or down) by differing amounts of gain.

Typically, the monitor recorder **14** will record a high resolution, low frequency signal for the P-wave segment. However, for some patients, the result may still be a visually small signal. Although high resolution is present, the unaided eye will normally be unable to discern the P-wave segment. Therefore, gaining the signal is critical to visually depicting P-wave detail. This technique works most efficaciously with a raw signal with low noise and high resolution, as generated by the monitor recorder **14**. Automatic gain control applied to a high noise signal will only exacerbate noise content and be self-defeating.

Finally, the download station can include filtering modules specifically intended to enhance P-wave content. For instance, a P-wave base boost filter **146**, which is a form of pre-emphasis filter, can be applied to the signal to restore missing frequency content or to correct phase distortion. Still other filters and types of signal processing are possible.

Conventional ECG monitors, like Holter monitors, invariably require specialized training on proper placement of leads and on the operation of recording apparatuses, plus support equipment purpose-built to retrieve, convert, and store ECG monitoring data. In contrast, the electrocardiography monitor **12** simplifies monitoring from end to end, starting with placement, then with use, and finally with data retrieval. FIGS. **16**A-C are functional block diagrams

respectively showing practical uses **150**, **160**, **170** of the extended wear electrocardiography monitors **12** of FIGS. **1** and **2**. The combination of a flexible extended wear electrode patch and a removable reusable (or single use) monitor recorder empowers physicians and patients alike with the ability to readily perform long-term ambulatory monitoring of the ECG and physiology.

Especially when compared to existing Holter-type monitors and monitoring patches placed in the upper pectoral region, the electrocardiography monitor **12** offers superior patient comfort, convenience and user-friendliness. To start, the electrode patch **15** is specifically designed for ease of use by a patient (or caregiver); assistance by professional medical personnel is not required. Moreover, the patient is free to replace the electrode patch **15** at any time and need not wait for a doctor's appointment to have a new electrode patch **15** placed. In addition, the monitor recorder **14** operates automatically and the patient only need snap the monitor recorder **14** into place on the electrode patch **15** to initiate ECG monitoring. Thus, the synergistic combination of the electrode patch **15** and monitor recorder **14** makes the use of the electrocardiography monitor **12** a reliable and virtually foolproof way to monitor a patient's ECG and physiology for an extended, or even open-ended, period of time.

In simplest form, extended wear monitoring can be performed by using the same monitor recorder **14** inserted into a succession of fresh new electrode patches **15**. As needed, the electrode patch **15** can be replaced by the patient (or caregiver) with a fresh new electrode patch **15** throughout the overall monitoring period. Referring first to FIG. **16**A, at the outset of monitoring, a patient adheres a new electrode patch **15** in a location at the sternal midline **16** (or immediately to either side of the sternum **13**) oriented top-to-bottom (step **151**). The placement of the wearable monitor in a location at the sternal midline (or immediately to either side of the sternum), with its unique narrow "hourglass"-like shape, significantly improves the ability of the wearable monitor to cutaneously sense cardiac electrical potential signals, particularly the P-wave (or atrial activity) and, to a lesser extent, the QRS interval signals indicating ventricular activity in the ECG waveforms.

Placement involves simply adhering the electrode patch **15** on the skin along the sternal midline **16** (or immediately to either side of the sternum **13**). Patients can easily be taught to find the physical landmarks on the body necessary for proper placement of the electrode patch **15**. The physical landmarks are locations on the surface of the body that are already familiar to patients, including the inter-mammary cleft between the breasts above the manubrium (particularly easily locatable by women and gynecomastic men), the sternal notch immediately above the manubrium, and the Xiphoid process located at the bottom of the sternum. Empowering patients with the knowledge to place the electrode patch **15** in the right place ensures that the ECG electrodes will be correctly positioned on the skin, no matter the number of times that the electrode patch **15** is replaced.

A monitor recorder **14** is snapped into the non-conductive receptacle **25** on the outward-facing surface of the electrode patch **15** (step **152**). The monitor recorder **14** draws power externally from a battery provided in the non-conductive receptacle **25**. In addition, the battery is replaced each time that a fresh new electrode patch **15** is placed on the skin, which ensures that the monitor recorder **14** is always operating with a fresh power supply and minimizing the chances of a loss of monitoring continuity due to a depleted battery source.

By default, the monitor recorder **14** automatically initiates monitoring upon sensing body surface potentials through the pair of ECG electrodes (step **153**). In a further embodiment, the monitor recorder **14** can be configured for manual operation, such as by using the tactile feedback button **66** on the outside of the sealed housing **50**, or other user-operable control. In an even further embodiment, the monitor recorder **14** can be configured for remotely-controlled operation by equipping the monitor recorder **14** with a wireless transceiver, such as described in commonly-assigned U.S. Pat. No. 9,433,367, issued Sep. 6, 2016, the disclosure of which is incorporated by reference. The wireless transceiver allows wearable or mobile communications devices to wirelessly interface with the monitor recorder **14**.

A key feature of the extended wear electrocardiography monitor **12** is the ability to monitor ECG and physiological data for an extended period of time, which can be well in excess of the 14 days currently pitched as being achievable by conventional ECG monitoring approaches. In a further embodiment, ECG monitoring can even be performed over an open-ended time period, as further explained infra. The monitor recorder **14** is reusable and, if so desired, can be transferred to successive electrode patches **15** to ensure continuity of monitoring. At any point during ECG monitoring, a patient (or caregiver) can remove the monitor recorder **14** (step **154**) and replace the electrode patch **15** currently being worn with a fresh new electrode patch **15** (step **151**). The electrode patch **15** may need to be replaced for any number of reasons. For instance, the electrode patch **15** may be starting to come off after a period of wear or the patient may have skin that is susceptible to itching or irritation. The wearing of ECG electrodes can aggravate such skin conditions. Thus, a patient may want or need to periodically remove or replace ECG electrodes during a long-term ECG monitoring period, whether to replace a dislodged electrode, reestablish better adhesion, alleviate itching or irritation, allow for cleansing of the skin, allow for showering and exercise, or for other purpose.

Following replacement, the monitor recorder **14** is again snapped into the electrode patch **15** (step **152**) and monitoring resumes (step **153**). The ability to transfer the same monitor recorder **14** to successive electrode patches **15** during a period of extended wear monitoring is advantageous not to just diagnose cardiac rhythm disorders and other physiological events of potential concern, but to do extremely long term monitoring, such as following up on cardiac surgery, ablation procedures, or medical device implantation. In these cases, several weeks of monitoring or more may be needed. In addition, some IMDs, such as pacemakers or implantable cardioverter defibrillators, incorporate a loop recorder that will capture cardiac events over a fixed time window. If the telemetry recorded by the IMD is not downloaded in time, cardiac events that occurred at a time preceding the fixed time window will be overwritten by the IMD and therefore lost. The monitor recorder **14** provides continuity of monitoring that acts to prevent loss of cardiac event data. In a further embodiment, the firmware executed by the microcontroller **61** of the monitor recorder **14** can be optimized for minimal power consumption and additional flash memory for storing monitoring data can be added to achieve a multi-week monitor recorder **14** that can be snapped into a fresh new electrode patch **15** every seven days, or other interval, for weeks or even months on end.

Upon the conclusion of monitoring, the monitor recorder **14** is removed (step **154**) and recorded ECG and physiological telemetry are downloaded (step **155**). For instance, a download station can be physically interfaced to the external

connector **65** of the monitor recorder **14** to initiate and conduct downloading, as described supra with reference to FIG. **15**.

In a further embodiment, the monitoring period can be of indeterminate duration. Referring next to FIG. **16**B, a similar series of operations are followed with respect to replacement of electrode patches **15**, reinsertion of the same monitor recorder **14**, and eventual download of ECG and physiological telemetry (steps **161**-**165**), as described supra with reference to FIG. **16**A. However, the flash memory **62** (shown in FIG. **9**) in the circuitry **60** of the monitor recorder **14** has a finite capacity. Following successful downloading of stored data, the flash memory **62** can be cleared to restore storage capacity and monitoring can resume once more, either by first adhering a new electrode patch **15** (step **161**) or by snapping the monitor recorder **14** into an already-adhered electrode patch **15** (step **162**). The foregoing expanded series of operations, to include reuse of the same monitor recorder **14** following data download, allows monitoring to continue indefinitely and without the kinds of interruptions that often affect conventional approaches, including the retrieval of monitoring data only by first making an appointment with a medical professional.

In a still further embodiment, when the monitor recorder **14** is equipped with a wireless transceiver, the use of a download station can be skipped. Referring last to FIG. **16**C, a similar series of operations are followed with respect to replacement of electrode patches **15** and reinsertion of the same monitor recorder **14** (steps **171**-**174**), as described supra with reference to FIG. **16**A. However, recorded ECG and physiological telemetry are downloaded wirelessly (step **175**), such as described in commonly-assigned U.S. Pat. No. 9,433,367, cited supra. The recorded ECG and physiological telemetry can even be downloaded wirelessly directly from a monitor recorder **14** during monitoring while still snapped into the non-conductive receptacle **25** on the electrode patch **15**. The wireless interfacing enables monitoring to continue for an open-ended period of time, as the downloading of the recorded ECG and physiological telemetry will continually free up onboard storage space. Further, wireless interfacing simplifies patient use, as the patient (or caregiver) only need worry about placing (and replacing) electrode patches **15** and inserting the monitor recorder **14**. Still other forms of practical use of the extended wear electrocardiography monitors **12** are possible.

The circuit trace and ECG electrodes components of the electrode patch **15** can be structurally simplified. In a still further embodiment, the flexible circuit **32** (shown in FIG. **5**) and distal ECG electrode **38** and proximal ECG electrode **39** (shown in FIG. **6**) are replaced with a pair of interlaced flexile wires. The interlacing of flexile wires through the flexible backing **20** reduces both manufacturing costs and environmental impact, as further described infra. The flexible circuit and ECG electrodes are replaced with a pair of flexile wires that serve as both electrode circuit traces and electrode signal pickups. FIG. **17** is a perspective view **180** of an extended wear electrode patch **15** with a flexile wire electrode assembly in accordance with a still further embodiment. The flexible backing **20** maintains the unique narrow "hourglass"-like shape that aids long term extended wear, particularly in women, as described supra with reference to FIG. **4**. For clarity, the non-conductive receptacle **25** is omitted to show the exposed battery printed circuit board **182** that is adhered underneath the non-conductive receptacle **25** to the proximal end **31** of the flexible backing **20**. Instead of employing flexible circuits, a pair of flexile wires are separately interlaced or sewn into the flexible backing **20** to serve as circuit connections for an anode electrode lead and for a cathode electrode lead.

To form a distal electrode assembly, a distal wire **181** is interlaced into the distal end **30** of the flexible backing **20**, continues along an axial path through the narrow longitudinal midsection of the elongated strip, and electrically connects to the battery printed circuit board **182** on the proximal end **31** of the flexible backing **20**. The distal wire **181** is connected to the battery printed circuit board **182** by stripping the distal wire **181** of insulation, if applicable, and interlacing or sewing the uninsulated end of the distal wire **181** directly into an exposed circuit trace **183**. The distal wire-to-battery printed circuit board connection can be made, for instance, by back stitching the distal wire **181** back and forth across the edge of the battery printed circuit board **182**. Similarly, to form a proximal electrode assembly, a proximal wire (not shown) is interlaced into the proximal end **31** of the flexible backing **20**. The proximal wire is connected to the battery printed circuit board **182** by stripping the proximal wire of insulation, if applicable, and interlacing or sewing the uninsulated end of the proximal wire directly into an exposed circuit trace **184**. The resulting flexile wire connections both establish electrical connections and help to affix the battery printed circuit board **182** to the flexible backing **20**.

The battery printed circuit board **182** is provided with a battery compartment **36**. A set of electrical pads **34** are formed on the battery printed circuit board **182**. The electrical pads **34** electrically interface the battery printed circuit board **182** with a monitor recorder **14** when fitted into the non-conductive receptacle **25**. The battery compartment **36** contains a spring **185** and a clasp **186**, or similar assembly, to hold a battery (not shown) in place and electrically interfaces the battery to the electrical pads **34** through a pair battery leads **187** for powering the electrocardiography monitor **14**. Other types of battery compartment are possible. The battery contained within the battery compartment **36** can be replaceable, rechargeable, or disposable.

In a yet further embodiment, the circuit board and non-conductive receptacle **25** are replaced by a combined housing that includes a battery compartment and a plurality of electrical pads. The housing can be affixed to the proximal end of the elongated strip through the interlacing or sewing of the flexile wires or other wires or threads.

The core of the flexile wires may be made from a solid, stranded, or braided conductive metal or metal compounds. In general, a solid wire will be less flexible than a stranded wire with the same total cross-sectional area, but will provide more mechanical rigidity than the stranded wire. The conductive core may be copper, aluminum, silver, or other material. The pair of the flexile wires may be provided as insulated wire. In one embodiment, the flexile wires are made from a magnet wire from Belden Cable, catalogue number 8051, with a solid core of AWG 22 with bare copper as conductor material and insulated by polyurethane or nylon. Still other types of flexile wires are possible. In a further embodiment, conductive ink or graphene can be used to print electrical connections, either in combination with or in place of the flexile wires.

In a still further embodiment, the flexile wires are uninsulated. FIG. **18** is perspective view of the flexile wire electrode assembly from FIG. **17**, with a layer of insulating material **189** shielding a bare uninsulated distal wire **181** around the midsection on the contact side of the flexible backing. On the contact side of the proximal and distal ends of the flexible backing, only the portions of the flexile wires serving as electrode signal pickups are electrically exposed

and the rest of the flexile wire on the contact side outside of the proximal and distal ends are shielded from electrical contact. The bare uninsulated distal wire **181** may be insulated using a layer of plastic, rubber-like polymers, or varnish, or by an additional layer of gauze or adhesive (or non-adhesive) gel. The bare uninsulated wire **181** on the non-contact side of the flexible backing may be insulated or can simply be left uninsulated.

Both end portions of the pair of flexile wires are typically placed uninsulated on the contact surface of the flexible backing **20** to form a pair of electrode signal pickups. FIG. **19** is a bottom view **190** of the flexile wire electrode assembly as shown in FIG. **17**. When adhered to the skin during use, the uninsulated end portions of the distal wire **181** and the proximal wire **191** enable the monitor recorder **14** to measure dermal electrical potential differentials. At the proximal and distal ends of the flexible backing **20**, the uninsulated end portions of the flexile wires may be configured into an appropriate pattern to provide an electrode signal pickup, which would typically be a spiral shape formed by guiding the flexile wire along an inwardly spiraling pattern. The surface area of the electrode pickups can also be variable, such as by selectively removing some or all of the insulation on the contact surface. For example, an electrode signal pickup arranged by sewing insulated flexile wire in a spiral pattern could have a crescent-shaped cutout of uninsulated flexile wire facing towards the signal source.

In a still yet further embodiment, the flexile wires are left freely riding on the contact surfaces on the distal and proximal ends of the flexible backing, rather than being interlaced into the ends of the flexible backing **20**. FIG. **20** is a bottom view **200** of a flexile wire electrode assembly in accordance with a still yet further embodiment. The distal wire **181** is interlaced onto the midsection and extends an exposed end portion **192** onto the distal end **30**. The proximal wire **191** extends an exposed end portion **193** onto the proximal end **31**. The exposed end portions **192** and **193**, not shielded with insulation, are further embedded within an electrically conductive adhesive **201**. The adhesive **201** makes contact to skin during use and conducts skin electrical potentials to the monitor recorder **14** (not shown) via the flexile wires. The adhesive **201** can be formed from electrically conductive, non-irritating adhesive, such as hydrocolloid.

The distal wire **181** is interlaced or sewn through the longitudinal midsection of the flexible backing **20** and takes the place of the flexible circuit **32**. FIG. **21** is a perspective view showing the longitudinal midsection of the flexible backing of the electrode assembly from FIG. **17**. Various stitching patterns may be adopted to provide a proper combination of rigidity and flexibility. In simplest form, the distal wire **181** can be manually threaded through a plurality of holes provided at regularly-spaced intervals along an axial path defined between the battery printed circuit board **182** (not shown) and the distal end **30** of the flexible backing **20**. The distal wire **181** can be threaded through the plurality of holes by stitching the flexile wire as a single "thread." Other types of stitching patterns or stitching of multiple "threads" could also be used, as well as using a sewing machine or similar device to machine-stitch the distal wire **181** into place, as further described infra. Further, the path of the distal wire **181** need not be limited to a straight line from the distal to the proximal end of the flexible backing **20**.

While the invention has been particularly shown and described as referenced to the embodiments thereof, those skilled in the art will understand that the foregoing and other changes in form and detail may be made therein without departing from the spirit and scope.

What is claimed is:

1. A moisture-resistant electrocardiography monitor, comprising:

an electrocardiography monitor recorder, comprising:

a wearable housing molded out of one or more materials and sealed against moisture;

a plurality of electrical contacts protruding from the wearable housing;

a seal coupling positioned on the wearable housing and surrounding the electrical contacts; and

electronic circuitry provided within the wearable housing, the electronic circuitry further comprising:

an electrocardiographic front end circuit under a control of a micro-controller and adapted to sense cardiac electrical potential differentials through electrocardiographic electrodes via some of the electrical contacts, which are provided to the micro-controller as an analog signal;

the micro-controller configured to sample the analog signal; and

a memory electrically interfaced with the micro-controller and operable to store the samples; and

an extended wear electrode patch, comprising:

a flexible backing comprising a plurality of adhesive contact surfaces;

the electrocardiographic electrodes, each comprised on one of the adhesive contact surfaces;

a receptacle affixed to a non-contacting surface of the flexible backing into which the wearable housing can be removably secured, the receptacle comprising a compartment within which a component interfaced to the electronic circuitry is positioned via some of the electrical contacts, wherein the component is a battery;

a plurality of electrical pads positioned on the receptacle, each of the pads configured to interface with one of the electrical contacts when the wearable housing is secured within the receptacle; and

a moisture-resistant seal formed on the receptacle and surrounding the electrical pads, wherein the moisture-resistant seal mates the seal coupling when the wearable housing is secured within the receptacle.

2. A monitor according to claim **1**, wherein the one or more materials comprise at least one of polycarbonate and ABS.

3. A monitor according to claim **1**, wherein the one or more materials comprise an alloy of polycarbonate and ABS.

4. A monitor according to claim **1**, the housing further comprising a waterproof patient-operable tactile-feedback button.

5. A monitor according to claim **4**, wherein an outer surface of the button is molded out of a soft pliable material.

6. A monitor according to claim **5**, wherein the soft pliable material comprises silicon rubber.

7. A monitor according to claim **1**, wherein the seal coupling and the moisture resistant seal are circular.

8. A monitor according to claim **1**, wherein the battery is replaceable without opening the wearable housing.

9. A monitor according to claim **1**, wherein the compartment is formed on a bottom surface of the receptacle.

10. A moisture-resistant patient-interfacing electrocardiography monitor, comprising:

an electrocardiography monitor recorder, comprising:

a wearable housing molded out of one or more materials and sealed against moisture;

a waterproof patient-operable tactile feedback button positioned on an outside of the wearable housing;

a plurality of electrical contacts protruding the wearable housing;

a seal coupling positioned on the wearable housing and surrounding the electrical contacts; and

electronic circuitry provided within the wearable housing, the electronic circuitry further comprising:

an electrocardiographic front end circuit under a control of a micro-controller and adapted to sense cardiac electrical potential differentials through electrocardiographic electrodes via some of the electrical contacts, which are provided to the micro-controller as an analog signal;

the micro-controller configured to sample the analog signal; and

a memory electrically interfaced with the micro-controller and operable to store the samples; and

an extended wear electrode patch, comprising:

a flexible backing comprising a plurality of adhesive contact surfaces;

the electrocardiographic electrodes, each comprised on one of the adhesive contact surfaces;

a receptacle affixed to a non-contacting surface of the flexible backing into which the wearable housing can be removably secured, the receptacle comprising a compartment within which a battery, wherein the electronic circuitry is powered by the battery via at least some of the electrical contacts;

a plurality of electrical pads positioned on the receptacle, each of the pads configured to interface with one of the electrical contacts when the wearable housing is secured within the receptacle; and

a moisture-resistant seal formed on the receptacle and surrounding the electrical pads, wherein the moisture-resistant seal mates the seal coupling when the wearable housing is secured within the receptacle.

11. A monitor according to claim **10**, wherein the one or more materials comprise at least one of polycarbonate and ABS.

12. A monitor according to claim **10**, wherein the one or more materials comprise an alloy of polycarbonate and ABS.

13. A monitor according to claim **10**, wherein the waterproof patient-operable tactile feedback button is positioned on a side of the housing opposite to a further side on which the electrical contacts are positioned.

14. A monitor according to claim **13**, wherein an outer surface of the button is molded out of a soft pliable material.

15. A monitor according to claim **14**, wherein the soft pliable material comprises silicon rubber.

16. A monitor according to claim **10**, wherein the seal coupling and the moisture resistant seal are circular.

17. A monitor according to claim **10**, wherein the battery is one of a replaceable, rechargeable, and disposable battery.

18. A monitor according to claim **10**, wherein the compartment is formed on a bottom surface of the receptacle.

19. A monitor according to claim **10**, wherein the battery is replaceable without opening the wearable housing.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 12,285,261 B2
APPLICATION NO. : 18/318641
DATED : April 29, 2025
INVENTOR(S) : Jason Felix, Jon Mikalson Bishay and Gust H. Bardy

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page

Item (54) and in the Specification, Column 1, Line 1:
The title should read: “MOISTURE-RESISTANT ELECTROCARDIOGRAPHY MONITOR” instead of “MOISTURE-RESISTANT ELECTROCARDIOGRAMY MONITOR”

Signed and Sealed this
Twenty-fourth Day of June, 2025

Coke Morgan Stewart
Acting Director of the United States Patent and Trademark Office

US012310735B2

(12) **United States Patent**
Felix et al.

(10) **Patent No.: US 12,310,735 B2**
(45) **Date of Patent: *May 27, 2025**

(54) **EXTENDED WEAR AMBULATORY ELECTROCARDIOGRAPHY MONITOR**

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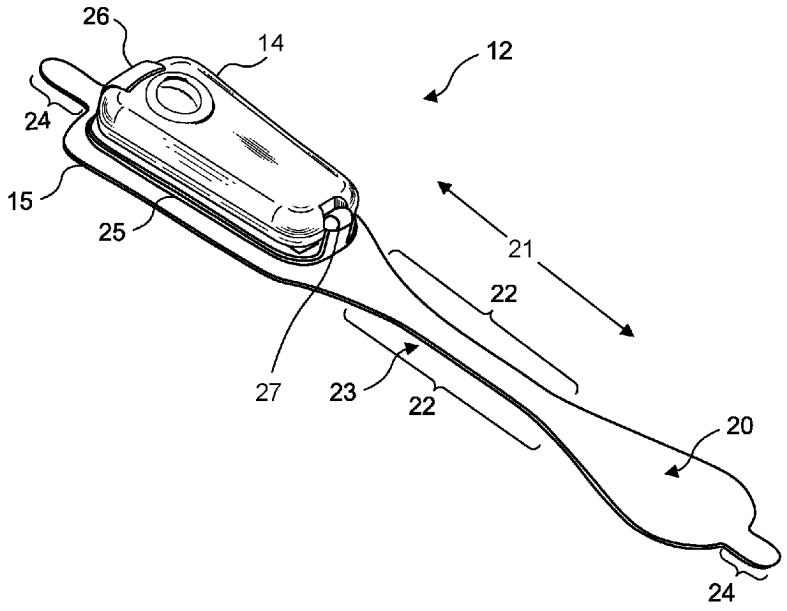
(57) **ABSTRACT**

An electrocardiography monitor is provided. A sealed housing includes one end wider than an opposite end of the sealed housing. Electronic circuitry is provided within the sealed housing. The electronic circuitry includes an electrographic front end circuit to sense electrocardiographic signals and a micro-controller interfaced to the electrocardiographic front end circuit to sample the electrocardiographic signals. A buzzer within the housing outputs feedback to a wearer of the sealed housing.

20 Claims, 6 Drawing Sheets



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[CORRECTED] Chart C-2 Invalidity Contentions: U.S. Pat. No. 11,051,743; Case No. 22-351-CJB (Delaware); Invalidity of U.S. Pat. No. 11,051,743 by U.S. Pat. Pub. No. 2011/0077497 ("Oster") and U.S. Pat. No. 11,116,447 ("Yang"); Oct. 25, 2023; 22 pages.
[CORRECTED] Chart CC-2 Invalidity Contentions: U.S. Pat. No. 11,445,967; Case No. 22-351-CJB (Delaware); Invalidity of U.S.

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Fig. 1.

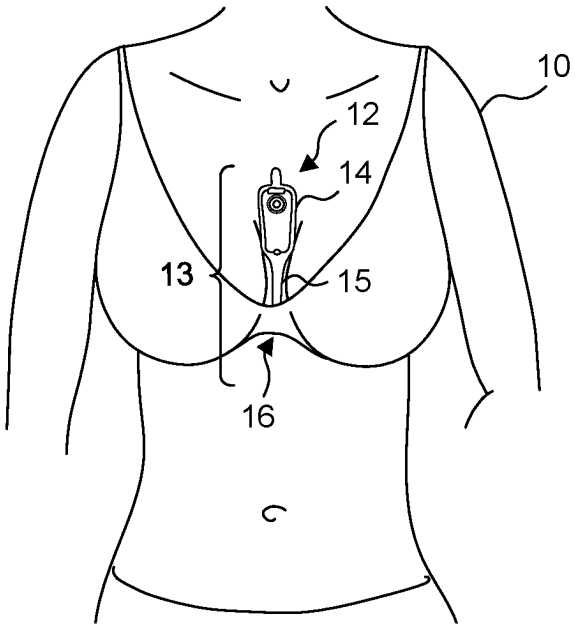
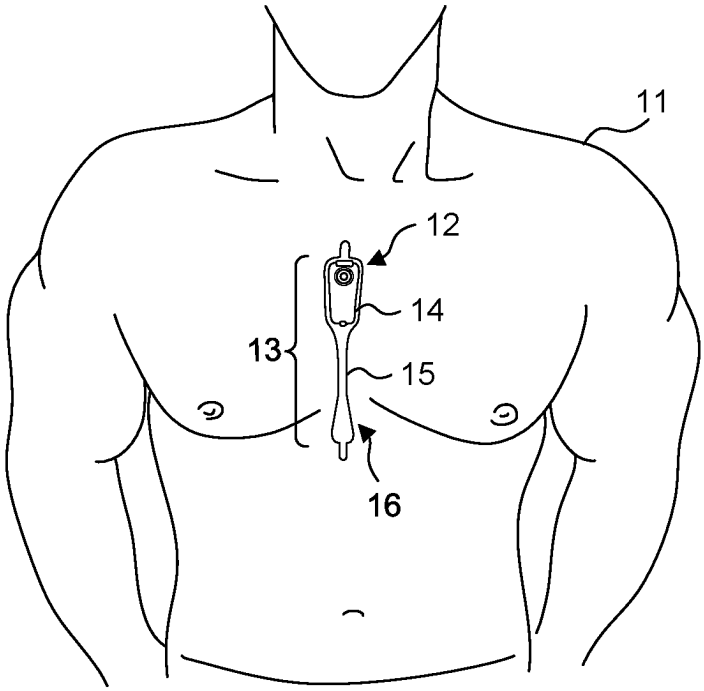


Fig. 2.



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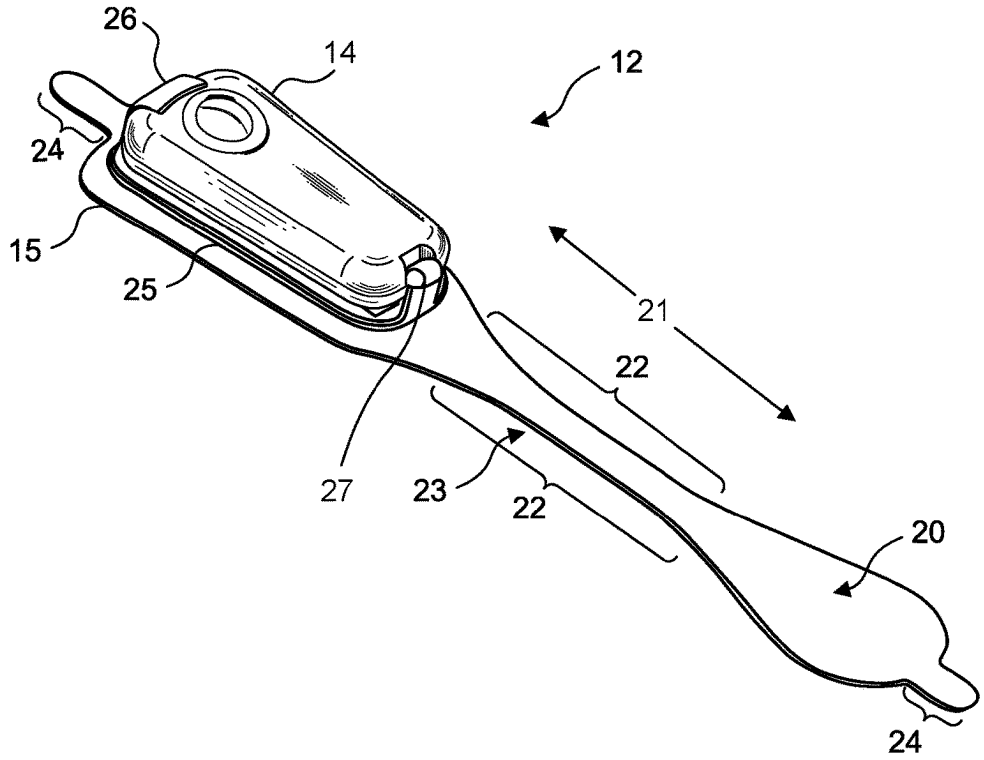
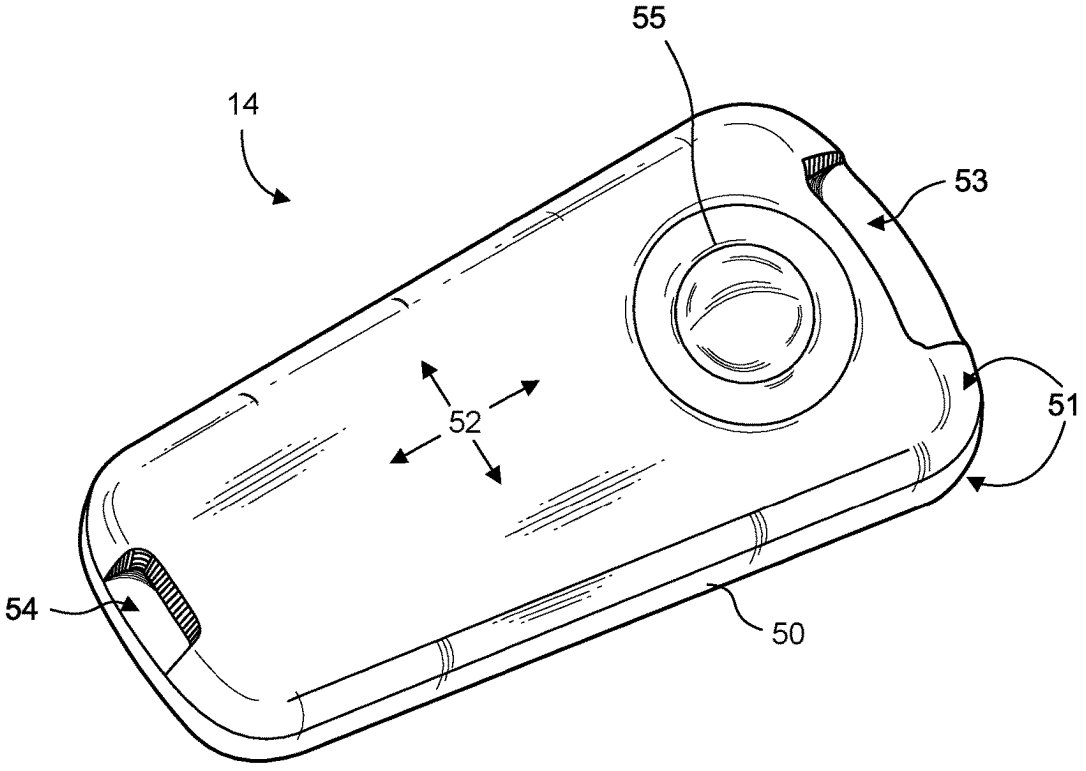


Fig. 4.



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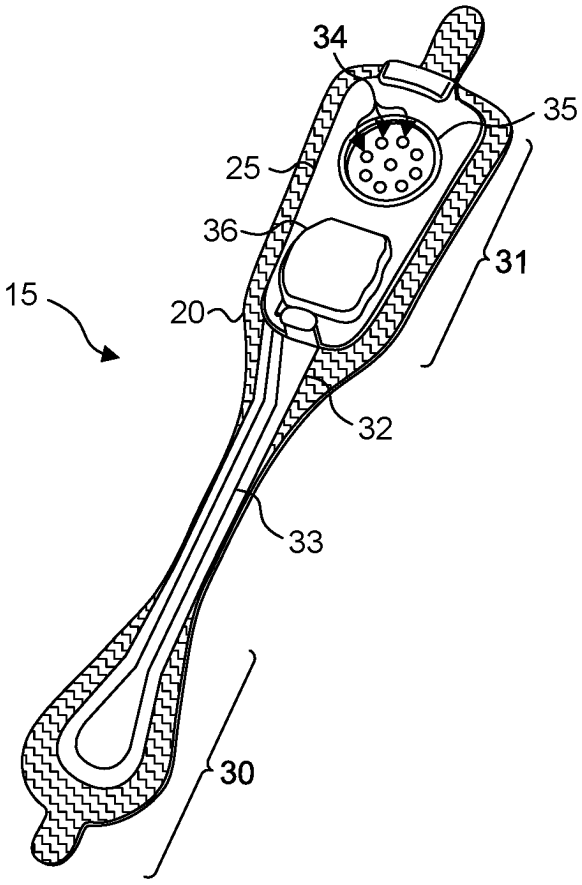

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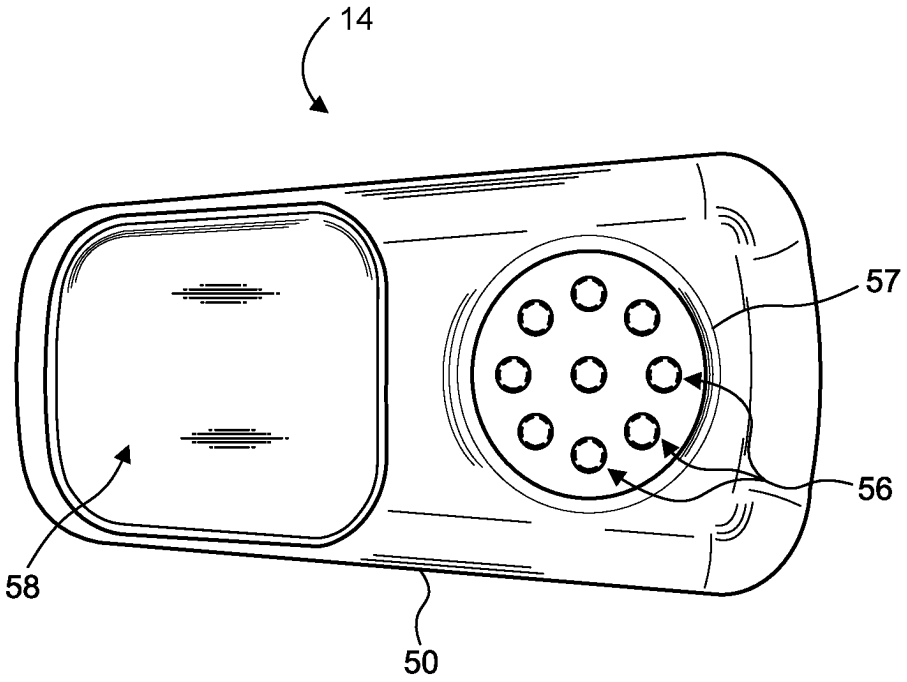


Fig. 7.

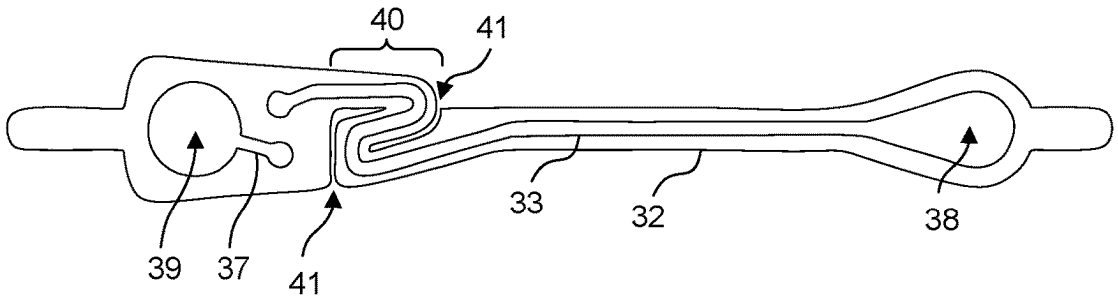


Fig. 8.

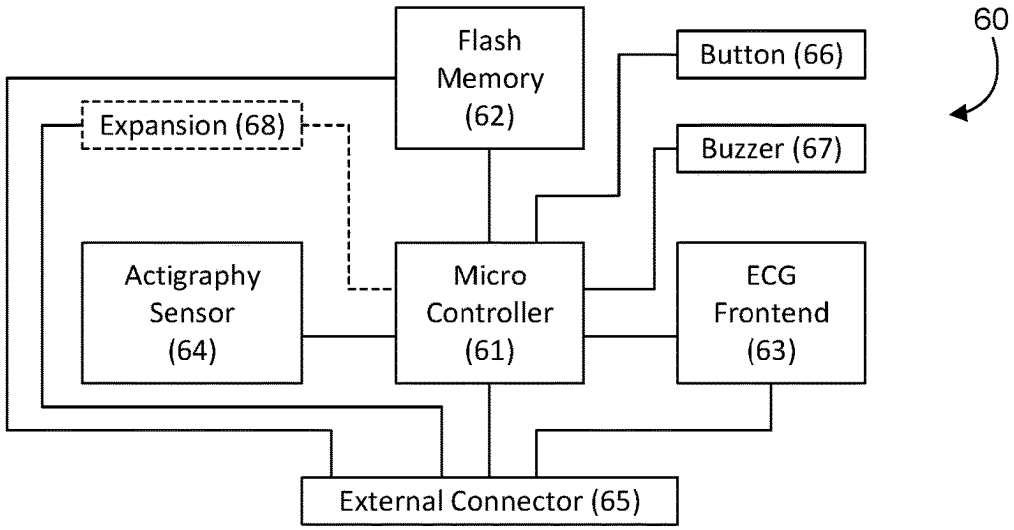


Fig. 9.

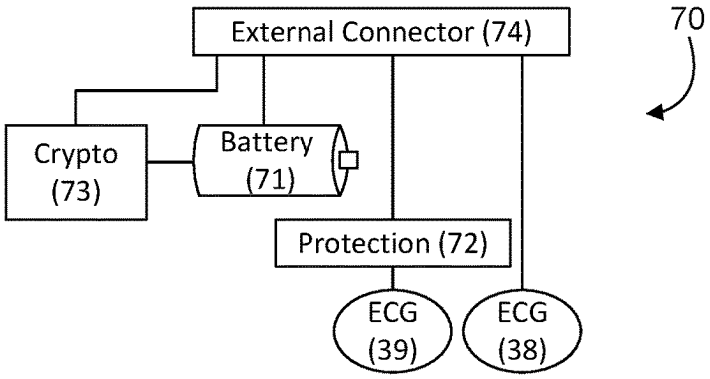
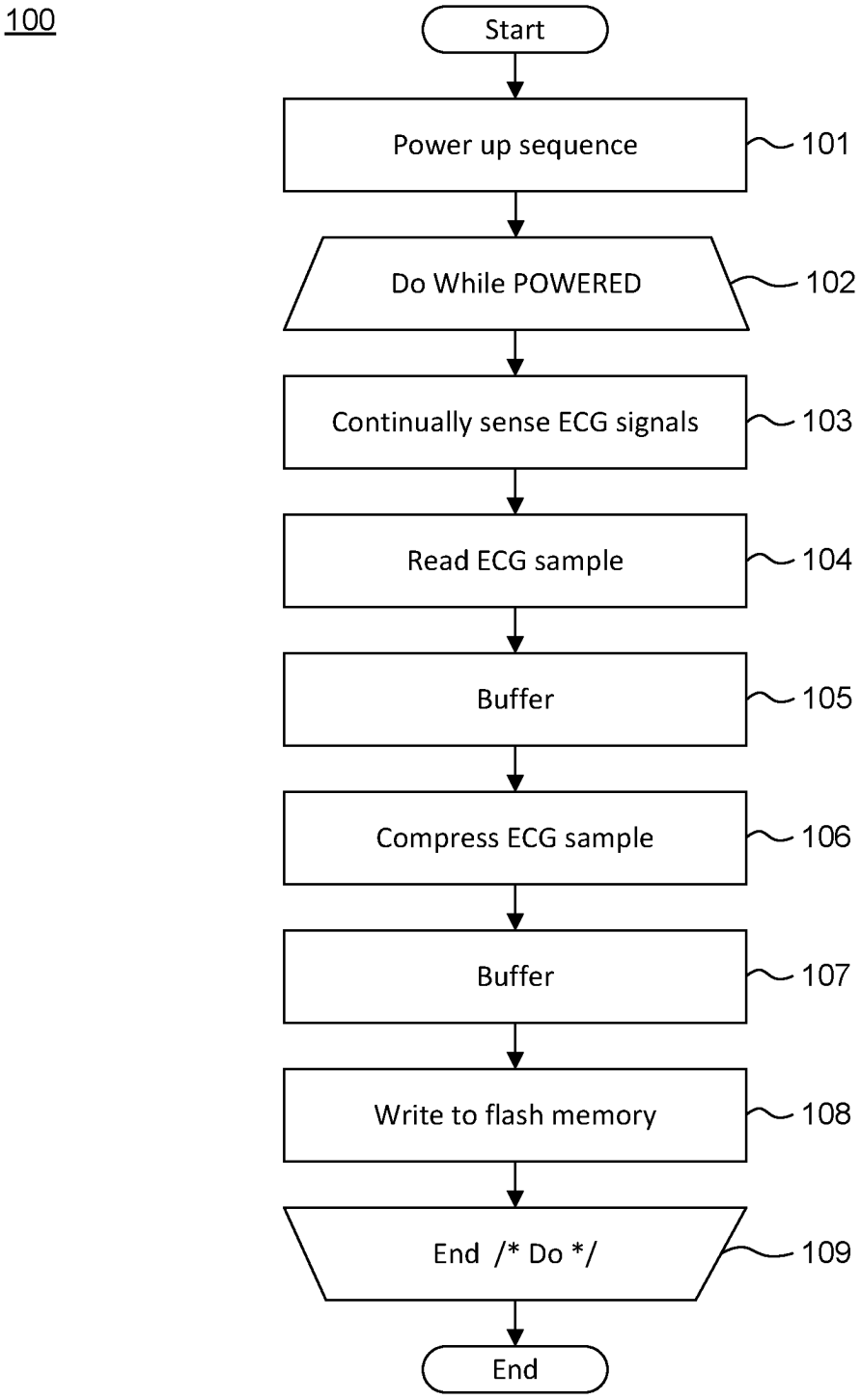


Fig. 10.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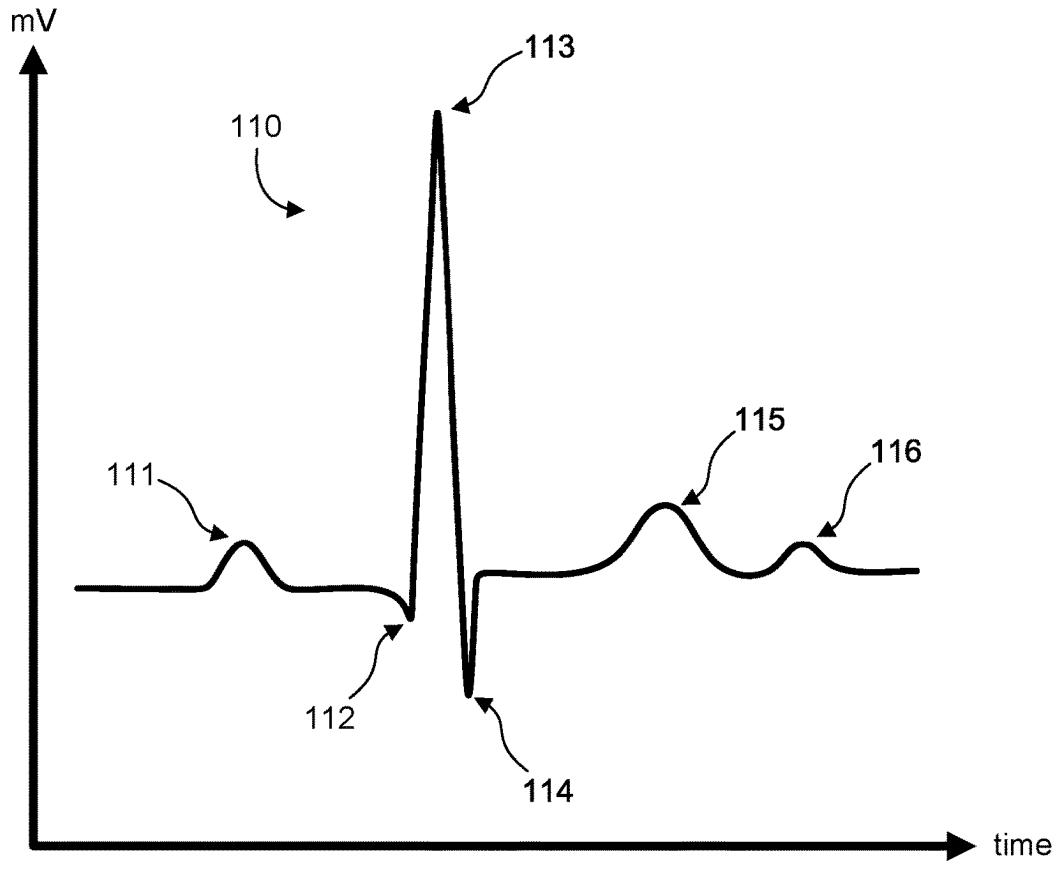
Start
Power up sequence
101
Do While POWERED
102
Continually sense ECG signals
103
Read ECG sample
104
Buffer
105
Compress ECG sample
106
Buffer
107
Write to flash memory
108
End /* Do */
109
End

Fig. 11.



EXTENDED WEAR AMBULATORY ELECTROCARDIOGRAPHY MONITOR

PRIORITY CLAIM AND CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 17/691,004, filed Mar. 9, 2022, titled EXTENDED WEAR AMBULATORY ELECTROCARDIOGRAPHY MONITOR, which is a continuation of U.S. patent application Ser. No. 16/684,386, filed Nov. 14, 2019, titled EXPENDED WEAR AMBULATORY ELECTROCARDIOGRAPHY AND PHYSIOLOGICAL SENSOR MONITOR, which is a continuation of U.S. patent application Ser. No. 15/676,896, filed Aug. 14, 2017, titled EXTENDED WEAR AMBULATORY ELECTROCARDIOGRAPHY AND PHYSIOLOGICAL SENSOR MONITOR, which is a continuation of U.S. patent application Ser. No. 14/080,725, filed Nov. 14, 2013, titled EXTENDED WEAR AMBULATORY ELECTROCARDIOGRAPHY AND PHYSIOLOGICAL SENSOR MONITOR, which claims priority to U.S. Provisional Patent App. No. 61/882,403, filed Sep. 25, 2013, titled LONG-TERM WEARABLE PHYSIOLOGICAL MONITOR. The entire contents of these applications are incorporated by reference herein in their entirely and relied upon.

FIELD

This application relates in general to electrocardiographic monitoring and, in particular, to an extended wear ambulatory electrocardiography monitor.

BACKGROUND

The heart emits electrical signals as a by-product of the propagation of the action potentials that trigger depolarization of heart fibers. An electrocardiogram (ECG) measures and records such electrical potentials to visually depict the electrical activity of the heart over time. Conventionally, a standardized set format 12-lead configuration is used by an ECG machine to record cardiac electrical signals from well-established traditional chest locations. Electrodes at the end of each lead are placed on the skin over the anterior thoracic region of the patient's body to the lower right and to the lower left of the sternum, on the left anterior chest, and on the limbs. Sensed cardiac electrical activity is represented by PQRSTU waveforms that can be interpreted post-ECG recordation to derive heart rate and physiology. The P-wave represents atrial electrical activity. The QRSTU components represent ventricular electrical activity.

An ECG is a tool used by physicians to diagnose heart problems and other potential health concerns. An ECG is a snapshot of heart function, typically recorded over 12 seconds, that can help diagnose rate and regularity of heartbeats, effect of drugs or cardiac devices, including pacemakers and implantable cardioverter-defibrillators (ICDs), and whether a patient has heart disease. ECGs are used in-clinic during appointments, and, as a result, are limited to recording only those heart-related aspects present at the time of recording. Sporadic conditions that may not show up during a spot ECG recording require other means to diagnose them. These disorders include fainting or syncope; rhythm disorders, such as tachyarrhythmias and bradyarrhythmias; apneic episodes; and other cardiac and related

disorders. Thus, an ECG only provides a partial picture and can be insufficient for complete patient diagnosis of many cardiac disorders.

Diagnostic efficacy can be improved, when appropriate, through the use of long-term extended ECG monitoring. Recording sufficient ECG and related physiology over an extended period is challenging, and often essential to enabling a physician to identify events of potential concern. A 30-day observation day period is considered the "gold standard" of ECG monitoring, yet achieving a 30-day observation day period has proven unworkable because such ECG monitoring systems are arduous to employ, cumbersome to the patient, and excessively costly. Ambulatory monitoring in-clinic is implausible and impracticable. Nevertheless, if a patient's ECG could be recorded in an ambulatory setting, thereby allowing the patient to engage in activities of daily living, the chances of acquiring meaningful information and capturing an abnormal event while the patient is engaged in normal activities becomes more likely to be achieved.

For instance, the long-term wear of ECG electrodes is complicated by skin irritation and the inability ECG electrodes to maintain continual skin contact after a day or two. Moreover, time, dirt, moisture, and other environmental contaminants, as well as perspiration, skin oil, and dead skin cells from the patient's body, can get between an ECG electrode, the non-conductive adhesive used to adhere the ECG electrode, and the skin's surface. All of these factors adversely affect electrode adhesion and the quality of cardiac signal recordings. Furthermore, the physical movements of the patient and their clothing impart various compressional, tensile, and torsional forces on the contact point of an ECG electrode, especially over long recording times, and an inflexibly fastened ECG electrode will be prone to becoming dislodged. Notwithstanding the cause of electrode dislodgment, depending upon the type of ECG monitor employed, precise re-placement of a dislodged ECG electrode maybe essential to ensuring signal capture at the same fidelity. Moreover, dislodgment may occur unbeknownst to the patient, making the ECG recordings worthless. Further, some patients may have skin that is susceptible to itching or irritation, and the wearing of ECG electrodes can aggravate such skin conditions. Thus, a patient may want or need to periodically remove or replace ECG electrodes during a long-term ECG monitoring period, whether to replace a dislodged electrode, reestablish better adhesion, alleviate itching or irritation, allow for cleansing of the skin, allow for showering and exercise, or for other purpose. Such replacement or slight alteration in electrode location actually facilitates the goal of recording the ECG signal for long periods of time.

Conventionally, Holter monitors are widely used for long-term extended ECG monitoring. Typically, they are often used for only 24-48 hours. A typical Holter monitor is a wearable and portable version of an ECG that include cables for each electrode placed on the skin and a separate battery-powered ECG recorder. The cable and electrode combination (or leads) are placed in the anterior thoracic region in a manner similar to what is done with an in-clinic standard ECG machine. The duration of a Holter monitoring recording depends on the sensing and storage capabilities of the monitor, as well as battery life. A "looping" Holter monitor (or event) can operate for a longer period of time by overwriting older ECG tracings, thence "recycling" storage in favor of extended operation, yet at the risk of losing event data. Although capable of extended ECG monitoring, Holter monitors are cumbersome, expensive and typically only available by medical prescription, which limits their usabil-

ity. Further, the skill required to properly place the electrodes on the patient's chest hinders or precludes a patient from replacing or removing the precordial leads and usually involves moving the patient from the physician office to a specialized center within the hospital or clinic.

The ZIO XT Patch and ZIO Event Card devices, manufactured by iRhythm Tech., Inc., San Francisco, CA, are wearable stick-on monitoring devices that are typically worn on the upper left pectoral region to respectively provide continuous and looping ECG recording. The location is used to simulate surgically implanted monitors. Both of these devices are prescription-only and for single patient use. The ZIO XT Patch device is limited to a 14-day monitoring period, while the electrodes only of the ZIO Event Card device can be worn for up to 30 days. The ZIO XT Patch device combines both electronic recordation components, including battery, and physical electrodes into a unitary assembly that adheres to the patient's skin. The ZIO XT Patch device uses adhesive sufficiently strong to support the weight of both the monitor and the electrodes over an extended period of time and to resist disadherance from the patient's body, albeit at the cost of disallowing removal or relocation during the monitoring period. Moreover, throughout monitoring, the battery is continually depleted and battery capacity can potentially limit overall monitoring duration. The ZIO Event Card device is a form of downsized Holter monitor with a recorder component that must be removed temporarily during baths or other activities that could damage the non-waterproof electronics. Both devices represent compromises between length of wear and quality of ECG monitoring, especially with respect to ease of long term use, female-friendly fit, and quality of atrial (P-wave) signals.

Therefore, a need remains for an extended wear continuously recording ECG monitor practicably capable of being worn for a long period of time in both men and women and capable of recording atrial signals reliably.

A further need remains for a device capable of recording signals ideal for arrhythmia discrimination, especially a device designed for atrial activity recording.

SUMMARY

Physiological monitoring can be provided through a wearable monitor that includes two components, a flexible extended wear electrode patch and a removable reusable monitor recorder. The wearable monitor sits centrally (in the midline) on the patient's chest along the sternum oriented top-to-bottom. The placement of the wearable monitor in a location at the sternal midline (or immediately to either side of the sternum), with its unique narrow "hourglass"-like shape, benefits long-term extended wear by removing the requirement that ECG electrodes be continually placed in the same spots on the skin throughout the monitoring period. Instead, the patient is free to place an electrode patch anywhere within the general region of the sternum. In addition, power is provided through a battery provided on the electrode patch, which avoids having to either periodically open the housing of the monitor recorder for the battery replacement, which also creates the potential for moisture intrusion and human error, or to recharge the battery, which can potentially take the monitor recorder off line for hours at a time. In addition, the electrode patch is intended to be disposable, while the monitor recorder is a reusable component. Thus, each time that the electrode patch is replaced, a fresh battery is provided for the use of the monitor recorder.

One embodiment provides an extended wear electrocardiography and physiological sensor monitor recorder that includes a sealed housing configured to be removably secured into a receptacle on an electrode patch that has a battery electrically interfaced to a pair of electrical pads on the receptacle. The sealed housing also includes a set of electrical contacts that protrude from a bottom surface and correspond with further electrical pads on the receptacle. Electronic circuitry is provided within the sealed housing and includes a micro-controller operable to execute under micro-programmable control, an electrographic front end circuit electrically interfaced to the micro-controller and operable to sense electrocardiographic signals through electrocardiographic electrodes provided on the electrode patch, and a flash memory electrically interfaced with the micro-controller and operable to store samples of the electrocardiographic signals.

A further embodiment provides an electrocardiography monitor. A sealed housing includes one end wider than an opposite end of the sealed housing. Electronic circuitry is provided within the sealed housing. The electronic circuitry includes an electrographic front end circuit to sense electrocardiographic signals and a micro-controller interfaced to the electrocardiographic front end circuit to sample the electrocardiographic signals. A buzzer within the housing outputs feedback to a wearer of the sealed housing.

A still further embodiment provides an extended wear electrocardiography and physiological sensor monitor that includes an electrode patch having a flexible backing formed of an elongated strip and a pair of electrocardiographic electrodes conductively exposed on a contact surface of each end of the elongated strip. A receptacle is adhered to an outward-facing side of the elongated strip opposite the contact surface and includes a plurality of electrical pads. A battery is electrically interfaced to a pair of the electrical pads on the receptacle. A flexible circuit is affixed on each end of the elongated strip and includes a pair of circuit traces electrically coupled to the pair of electrocardiographic electrodes and another pair of the electrical pads. An electrocardiography monitor includes a sealed housing configured to be removably secured into the receptacle on the electrode patch and has a set of electrical contacts that protrude from a bottom surface and correspond with further electrical pads on the receptacle. Electronic circuitry is provided within the sealed housing and includes a micro-controller operable to execute under micro-programmable control, an electrographic front end circuit electrically interfaced to the micro-controller and operable to sense electrocardiographic signals through the electrocardiographic electrodes provided on the electrode patch, and a flash memory electrically interfaced with the micro-controller and operable to store samples of the electrocardiographic signals.

The monitoring patch is especially suited to the female anatomy. The narrow longitudinal midsection can fit nicely within the intermammary cleft of the breasts without inducing discomfort, whereas conventional patch electrodes are wide and, if adhesed between the breasts, would cause chafing, irritation, frustration, and annoyance, leading to low patient compliance.

The foregoing aspects enhance ECG monitoring performance and quality facilitating long-term ECG recording, critical to accurate arrhythmia diagnosis.

In addition, the foregoing aspects enhance comfort in women (and certain men), but not irritation of the breasts, by placing the monitoring patch in the best location possible for optimizing the recording of cardiac signals from the atrium, another feature critical to proper arrhythmia diagnosis.

Still other embodiments will become readily apparent to those skilled in the art from the following detailed description, wherein are described embodiments by way of illustrating the best mode contemplated. As will be realized, other and different embodiments are possible and the embodiments' several details are capable of modifications in various obvious respects, all without departing from their spirit and the scope. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not as restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1** and **2** are diagrams showing, by way of examples, an extended wear electrocardiography and physiological sensor monitor, including a monitor recorder in accordance with one embodiment, respectively fitted to the sternal region of a female patient and a male patient.

FIG. **3** is a perspective view showing an extended wear electrode patch with a monitor recorder in accordance with one embodiment inserted.

FIG. **4** is a perspective view showing the monitor recorder of FIG. **3**.

FIG. **5** is a perspective view showing the extended wear electrode patch of FIG. **3** without a monitor recorder inserted.

FIG. **6** is a bottom plan view of the monitor recorder of FIG. **3**.

FIG. **7** is a top view showing the flexible circuit of the extended wear electrode patch of FIG. **3** when mounted above the flexible backing.

FIG. **8** is a functional block diagram showing the component architecture of the circuitry of the monitor recorder of FIG. **3**.

FIG. **9** is a functional block diagram showing the circuitry of the extended wear electrode patch of FIG. **3**.

FIG. **10** is a flow diagram showing a monitor recorder-implemented method for monitoring ECG data for use in the monitor recorder of FIG. **3**.

FIG. **11** is a graph showing, by way of example, a typical ECG waveform.

DETAILED DESCRIPTION

Physiological monitoring can be provided through a wearable monitor that includes two components, a flexible extended wear electrode patch and a removable reusable monitor recorder. FIGS. **1** and **2** are diagrams showing, by way of examples, an extended wear electrocardiography and physiological sensor monitor **12**, including a monitor recorder **14** in accordance with one embodiment, respectively fitted to the sternal region of a female patient **10** and a male patient **11**. The wearable monitor **12** sits centrally (in the midline) on the patient's chest along the sternum **13** oriented top-to-bottom with the monitor recorder **14** preferably situated towards the patient's head. In a further embodiment, the orientation of the wearable monitor **12** can be corrected post-monitoring, as further described infra. The electrode patch **15** is shaped to fit comfortably and conformal to the contours of the patient's chest approximately centered on the sternal midline **16** (or immediately to either side of the sternum **13**). The distal end of the electrode patch **15** extends towards the Xiphoid process and, depending upon the patient's build, may straddle the region over the Xiphoid process. The proximal end of the electrode patch **15**, located under the monitor recorder **14**, is below the manubrium and, depending upon patient's build, may straddle the region over the manubrium.

The placement of the wearable monitor **12** in a location at the sternal midline **16** (or immediately to either side of the sternum **13**) significantly improves the ability of the wearable monitor **12** to cutaneously sense cardiac electric signals, particularly the P-wave (or atrial activity) and, to a lesser extent, the QRS interval signals in the ECG waveforms that indicate ventricular activity. The sternum **13** overlies the right atrium of the heart and the placement of the wearable monitor **12** in the region of the sternal midline **13** puts the ECG electrodes of the electrode patch **15** in a location better adapted to sensing and recording P-wave signals than other placement locations, say, the upper left pectoral region. In addition, placing the lower or inferior pole (ECG electrode) of the electrode patch **15** over (or near) the Xiphoid process facilitates sensing of right ventricular activity and provides superior recordation of the QRS interval.

During use, the electrode patch **15** is first adhesed to the skin along the sternal midline **16** (or immediately to either side of the sternum **13**). A monitor recorder **14** is then snapped into place on the electrode patch **15** to initiate ECG monitoring. FIG. **3** is a perspective view showing an extended wear electrode patch **15** with a monitor recorder **14** in accordance with one embodiment inserted. The body of the electrode patch **15** is preferably constructed using a flexible backing **20** formed as an elongated strip **21** of wrap knit or similar stretchable material with a narrow longitudinal mid-section **23** evenly tapering inward from both sides. A pair of cut-outs **22** between the distal and proximal ends of the electrode patch **15** create a narrow longitudinal midsection **23** or "isthmus" and defines an elongated "hourglass"-like shape, when viewed from above.

The electrode patch **15** incorporates features that significantly improve wearability, performance, and patient comfort throughout an extended monitoring period. During wear, the electrode patch **15** is susceptible to pushing, pulling, and torqueing movements, including compressional and torsional forces when the patient bends forward, and tensile and torsional forces when the patient leans backwards. To counter these stress forces, the electrode patch **15** incorporates strain and crimp reliefs, such as described in commonly-assigned U.S. Patent, entitled "Extended Wear Electrocardiography Patch," U.S. Pat. No. 9,545,204, issued on Jan. 17, 2017, the disclosure of which is incorporated by reference. In addition, the cut-outs **22** and longitudinal midsection **23** help minimize interference with and discomfort to breast tissue, particularly in women (and gynecomastic men). The cut-outs **22** and longitudinal midsection **23** further allow better conformity of the electrode patch **15** to sternal bowing and to the narrow isthmus of flat skin that can occur along the bottom of the intermammary cleft between the breasts, especially in buxom women. The cut-outs **22** and longitudinal midsection **23** help the electrode patch **15** fit nicely between a pair of female breasts in the intermammary cleft. Still other shapes, cut-outs and conformities to the electrode patch **15** are possible.

The monitor recorder **14** removably and reusably snaps into an electrically non-conductive receptacle **25** during use. The monitor recorder **14** contains electronic circuitry for recording and storing the patient's electrocardiography as sensed via a pair of ECG electrodes provided on the electrode patch **15**, as further described infra beginning with reference to FIG. **8**. The non-conductive receptacle **25** is provided on the top surface of the flexible backing **20** with a retention catch **26** and tension clip **27** molded into the

non-conductive receptacle **25** to conformably receive and securely hold the monitor recorder **14** in place.

The monitor recorder **14** includes a sealed housing that snaps into place in the non-conductive receptacle **25**. FIG. **4** is a perspective view showing the monitor recorder **14** of FIG. **3**. The sealed housing **50** of the monitor recorder **14** intentionally has a rounded isosceles trapezoidal-like shape **52**, when viewed from above, such as described in commonly-assigned U.S. Design Patent, entitled "Electrocardiography Monitor," No. D717955, issued on Nov. 18, 2014, the disclosure of which is incorporated by reference. The edges **51** along the top and bottom surfaces are rounded for patient comfort. The sealed housing **50** is approximately 47 mm long, 23 mm wide at the widest point, and 7 mm high, excluding a patient-operable tactile-feedback button **55**. The sealed housing **50** can be molded out of polycarbonate, ABS, or an alloy of those two materials. The button **55** is waterproof and the button's top outer surface is molded silicon rubber or similar soft pliable material. A retention detent **53** and tension detent **54** are molded along the edges of the top surface of the housing **50** to respectively engage the retention catch **26** and the tension clip **27** molded into non-conductive receptacle **25**. Other shapes, features, and conformities of the sealed housing **50** are possible.

The electrode patch **15** is intended to be disposable. The monitor recorder **14**, however, is reusable and can be transferred to successive electrode patches **15** to ensure continuity of monitoring. The placement of the wearable monitor **12** in a location at the sternal midline **16** (or immediately to either side of the sternum **13**) benefits long-term extended wear by removing the requirement that ECG electrodes be continually placed in the same spots on the skin throughout the monitoring period. Instead, the patient is free to place an electrode patch **15** anywhere within the general region of the sternum **13**.

As a result, at any point during ECG monitoring, the patient's skin is able to recover from the wearing of an electrode patch **15**, which increases patient comfort and satisfaction, while the monitor recorder **14** ensures ECG monitoring continuity with minimal effort. A monitor recorder **14** is merely unsnapped from a worn out electrode patch **15**, the worn out electrode patch **15** is removed from the skin, a new electrode patch **15** is adhered to the skin, possibly in a new spot immediately adjacent to the earlier location, and the same monitor recorder **14** is snapped into the new electrode patch **15** to reinitiate and continue the ECG monitoring.

During use, the electrode patch **15** is first adhered to the skin in the sternal region. FIG. **5** is a perspective view showing the extended wear electrode patch **15** of FIG. **3** without a monitor recorder **14** inserted. A flexible circuit **32** is adhered to each end of the flexible backing **20**. A distal circuit trace **33** and a proximal circuit trace (not shown) electrically couple ECG electrodes (not shown) to a pair of electrical pads **34**. The electrical pads **34** are provided within a moisture-resistant seal **35** formed on the bottom surface of the non-conductive receptacle **25**. When the monitor recorder **14** is securely received into the non-conductive receptacle **25**, that is, snapped into place, the electrical pads **34** interface to electrical contacts (not shown) protruding from the bottom surface of the monitor recorder **14**, and the moisture-resistant seal **35** enables the monitor recorder **14** to be worn at all times, even during bathing or other activities that could expose the monitor recorder **14** to moisture.

In addition, a battery compartment **36** is formed on the bottom surface of the non-conductive receptacle **25**, and a pair of battery leads (not shown) electrically interface the battery to another pair of the electrical pads **34**. The battery contained within the battery compartment **35** can be replaceable, rechargeable or disposable.

The monitor recorder **14** draws power externally from the battery provided in the non-conductive receptacle **25**, thereby uniquely obviating the need for the monitor recorder **14** to carry a dedicated power source. FIG. **6** is a bottom plan view of the monitor recorder **14** of FIG. **3**. A cavity **58** is formed on the bottom surface of the sealed housing **50** to accommodate the upward projection of the battery compartment **36** from the bottom surface of the non-conductive receptacle **25**, when the monitor recorder **14** is secured in place on the non-conductive receptacle **25**. A set of electrical contacts **56** protrude from the bottom surface of the sealed housing **50** and are arranged in alignment with the electrical pads **34** provided on the bottom surface of the non-conductive receptacle **25** to establish electrical connections between the electrode patch **15** and the monitor recorder **14**. In addition, a seal coupling **57** circumferentially surrounds the set of electrical contacts **56** and securely mates with the moisture-resistant seal **35** formed on the bottom surface of the non-conductive receptacle **25**.

The placement of the flexible backing **20** on the sternal midline **16** (or immediately to either side of the sternum **13**) also helps to minimize the side-to-side movement of the wearable monitor **12** in the left- and right-handed directions during wear. To counter the dislodgment of the flexible backing **20** due to compressional and torsional forces, a layer of non-irritating adhesive, such as hydrocolloid, is provided at least partially on the underside, or contact, surface of the flexible backing **20**, but only on the distal end **30** and the proximal end **31**. As a result, the underside, or contact surface of the longitudinal midsection **23** does not have an adhesive layer and remains free to move relative to the skin. Thus, the longitudinal midsection **23** forms a crimp relief that respectively facilitates compression and twisting of the flexible backing **20** in response to compressional and torsional forces. Other forms of flexible backing crimp reliefs are possible.

Unlike the flexible backing **20**, the flexible circuit **32** is only able to bend and cannot stretch in a planar direction. The flexible circuit **32** can be provided either above or below the flexible backing **20**. FIG. **7** is a top view showing the flexible circuit **32** of the extended wear electrode patch **15** of FIG. **3** when mounted above the flexible backing **20**. A distal ECG electrode **38** and proximal ECG electrode **39** are respectively coupled to the distal and proximal ends of the flexible circuit **32**. A strain relief **40** is defined in the flexible circuit **32** at a location that is partially underneath the battery compartment **36** when the flexible circuit **32** is affixed to the flexible backing **20**. The strain relief **40** is laterally extendable to counter dislodgment of the ECG electrodes **38**, **39** due to tensile and torsional forces. A pair of strain relief cutouts **41** partially extend transversely from each opposite side of the flexible circuit **32** and continue longitudinally towards each other to define in 'S'-shaped pattern, when viewed from above. The strain relief respectively facilitates longitudinal extension and twisting of the flexible circuit **32** in response to tensile and torsional forces. Other forms of circuit board strain relief are possible.

ECG monitoring and other functions performed by the monitor recorder **14** are provided through a micro controlled architecture. FIG. **8** is a functional block diagram showing the component architecture of the circuitry **60** of the monitor recorder **14** of FIG. **3**. The circuitry **60** is externally powered through a battery provided in the non-conductive receptacle **25** (shown in FIG. **5**). Both power and raw ECG signals,

which originate in the pair of ECG electrodes **38**, **39** (shown in FIG. **7**) on the distal and proximal ends of the electrode patch **15**, are received through an external connector **65** that mates with a corresponding physical connector on the electrode patch **15**. The external connector **65** includes the set of electrical contacts **56** that protrude from the bottom surface of the sealed housing **50** and which physically and electrically interface with the set of pads **34** provided on the bottom surface of the non-conductive receptacle **25**. The external connector includes electrical contacts **56** for data download, microcontroller communications, power, analog inputs, and a peripheral expansion port. The arrangement of the pins on the electrical connector **65** of the monitor recorder **14** and the device into which the monitor recorder **14** is attached, whether an electrode patch **15** or download station (not shown), follow the same electrical pin assignment convention to facilitate interoperability. The external connector **65** also serves as a physical interface to a download station that permits the retrieval of stored ECG monitoring data, communication with the monitor recorder **14**, and performance of other functions.

Operation of the circuitry **60** of the monitor recorder **14** is managed by a microcontroller **61**. The micro-controller **61** includes a program memory unit containing internal flash memory that is readable and writeable. The internal flash memory can also be programmed externally. The microcontroller **61** draws power externally from the battery provided on the electrode patch **15** via a pair of the electrical contacts **56**. The microcontroller **61** connects to the ECG front end circuit **63** that measures raw cutaneous electrical signals and generates an analog ECG signal representative of the electrical activity of the patient's heart over time.

The circuitry **60** of the monitor recorder **14** also includes a flash memory **62**, which the micro-controller **61** uses for storing ECG monitoring data and other physiology and information. The flash memory **62** also draws power externally from the battery provided on the electrode patch **15** via a pair of the electrical contacts **56**. Data is stored in a serial flash memory circuit, which supports read, erase and program operations over a communications bus. The flash memory **62** enables the microcontroller **61** to store digitized ECG data. The communications bus further enables the flash memory **62** to be directly accessed externally over the external connector **65** when the monitor recorder **14** is interfaced to a download station.

The circuitry **60** of the monitor recorder **14** further includes an actigraphy sensor **64** implemented as a 3-axis accelerometer. The accelerometer may be configured to generate interrupt signals to the microcontroller **61** by independent initial wake up and free fall events, as well as by device position. In addition, the actigraphy provided by the accelerometer can be used during post-monitoring analysis to correct the orientation of the monitor recorder **14** if, for instance, the monitor recorder **14** has been inadvertently installed upside down, that is, with the monitor recorder **14** oriented on the electrode patch **15** towards the patient's feet, as well as for other event occurrence analyses.

The microcontroller **61** includes an expansion port that also utilizes the communications bus. External devices, separately drawing power externally from the battery provided on the electrode patch **15** or other source, can interface to the microcontroller **61** over the expansion port in half duplex mode. For instance, an external physiology sensor can be provided as part of the circuitry **60** of the monitor recorder **14**, or can be provided on the electrode patch **15** with communication with the micro-controller **61** provided over one of the electrical contacts **56**. The physiology sensor can include an SpO_2 sensor, blood pressure sensor, temperature sensor, respiratory rate sensor, glucose sensor, airflow sensor, volumetric pressure sensing, or other types of sensor or telemetric input sources. In a further embodiment, a wireless interface for interfacing with other wearable (or implantable) physiology monitors, as well as data offload and programming, can be provided as part of the circuitry **60** of the monitor recorder **14**, or can be provided on the electrode patch **15** with communication with the microcontroller **61** provided over one of the electrical contacts **56**.

Finally, the circuitry **60** of the monitor recorder **14** includes patient-interfaceable components, including a tactile feedback button **66**, which a patient can press to mark events or to perform other functions, and a buzzer **67**, such as a speaker, magnetic resonator or piezoelectric buzzer. The buzzer **67** can be used by the microcontroller **61** to output feedback to a patient such as to confirm power up and initiation of ECG monitoring. Still other components as part of the circuitry **60** of the monitor recorder **14** are possible.

While the monitor recorder **14** operates under micro control, most of the electrical components of the electrode patch **15** operate passively. FIG. **9** is a functional block diagram showing the circuitry **70** of the extended wear electrode patch **15** of FIG. **3**. The circuitry **70** of the electrode patch **15** is electrically coupled with the circuitry **60** of the monitor recorder **14** through an external connector **74**. The external connector **74** is terminated through the set of pads **34** provided on the bottom of the non-conductive receptacle **25**, which electrically mate to corresponding electrical contacts **56** protruding from the bottom surface of the sealed housing **50** to electrically interface the monitor recorder **14** to the electrode patch **15**.

The circuitry **70** of the electrode patch **15** performs three primary functions. First, a battery **71** is provided in a battery compartment formed on the bottom surface of the non-conductive receptacle **25**. The battery **71** is electrically interfaced to the circuitry **60** of the monitor recorder **14** as a source of external power. The unique provisioning of the battery **71** on the electrode patch **15** provides several advantages. First, the locating of the battery **71** physically on the electrode patch **15** lowers the center of gravity of the overall wearable monitor **12** and thereby helps to minimize shear forces and the effects of movements of the patient and clothing. Moreover, the housing **50** of the monitor recorder **14** is sealed against moisture and providing power externally avoids having to either periodically open the housing **50** for the battery replacement, which also creates the potential for moisture intrusion and human error, or to recharge the battery, which can potentially take the monitor recorder **14** off line for hours at a time. In addition, the electrode patch **15** is intended to be disposable, while the monitor recorder **14** is a reusable component. Each time that the electrode patch **15** is replaced, a fresh battery is provided for the use of the monitor recorder **14**, which enhances ECG monitoring performance quality and duration of use. Finally, the architecture of the monitor recorder **14** is open, in that other physiology sensors or components can be added by virtue of the expansion port of the microcontroller **61**. Requiring those additional sensors or components to draw power from a source external to the monitor recorder **14** keeps power considerations independent of the monitor recorder **14**. Thus, a battery of higher capacity could be introduced when needed to support the additional sensors or components without effecting the monitor recorders circuitry **60**.

Second, the pair of ECG electrodes **38**, **39** respectively provided on the distal and proximal ends of the flexible circuit **32** are electrically coupled to the set of pads **34**

provided on the bottom of the non-conductive receptacle **25** by way of their respective circuit traces **33**, **37**. The signal ECG electrode **39** includes a protection circuit **72**, which is an inline resistor that protects the patient from excessive leakage current.

Last, in a further embodiment, the circuitry **70** of the electrode patch **15** includes a cryptographic circuit **73** to authenticate an electrode patch **15** for use with a monitor recorder **14**. The cryptographic circuit **73** includes a device capable of secure authentication and validation. The cryptographic device **73** ensures that only genuine, non-expired, safe, and authenticated electrode patches **15** are permitted to provide monitoring data to a monitor recorder **14**.

The monitor recorder **14** continuously monitors the patient's heart rate and physiology. FIG. **10** is a flow diagram showing a monitor recorder-implemented method **100** for monitoring ECG data for use in the monitor recorder **14** of FIG. **3**. Initially, upon being connected to the set of pads **34** provided with the non-conductive receptacle **25** when the monitor recorder **14** is snapped into place, the microcontroller **61** executes a power up sequence (step **101**). During the power up sequence, the voltage of the battery **71** is checked, the state of the flash memory **62** is confirmed, both in terms of operability check and available capacity, and microcontroller operation is diagnostically confirmed. In a further embodiment, an authentication procedure between the microcontroller **61** and the electrode patch **15** are also performed.

Following satisfactory completion of the power up sequence, an iterative processing loop (steps **102**-**109**) is continually executed by the microcontroller **61**. During each iteration (step **102**) of the processing loop, the ECG frontend **63** (shown in FIG. **8**) continually senses the cutaneous ECG electrical signals (step **103**) via the ECG electrodes **38**, **29** and is optimized to maintain the integrity of the P-wave. A sample of the ECG signal is read (step **104**) by the microcontroller **61** by sampling the analog ECG signal output front end **63**. FIG. **11** is a graph showing, by way of example, a typical ECG waveform **110**. The x-axis represents time in approximate units of tenths of a second. The y-axis represents cutaneous electrical signal strength in approximate units of millivolts. The P-wave **111** has a smooth, normally upward, that is, positive, waveform that indicates atrial depolarization. The QRS complex usually begins with the downward deflection of a Q wave **112**, followed by a larger upward deflection of an R-wave **113**, and terminated with a downward waveform of the S wave **114**, collectively representative of ventricular depolarization. The T wave **115** is normally a modest upward waveform, representative of ventricular depolarization, while the U wave **116**, often not directly observable, indicates the recovery period of the Purkinje conduction fibers.

Sampling of the R-to-R interval enables heart rate information derivation. For instance, the R-to-R interval represents the ventricular rate and rhythm, while the P-to-P interval represents the atrial rate and rhythm. Importantly, the PR interval is indicative of atrioventricular (AV) conduction time and abnormalities in the PR interval can reveal underlying heart disorders, thus representing another reason why the P-wave quality achievable by the extended wear ambulatory electrocardiography and physiological sensor monitor described herein is medically unique and important. The long-term observation of these ECG indicia, as provided through extended wear of the wearable monitor **12**, provides valuable insights to the patient's cardiac function and overall well-being.

Each sampled ECG signal, in quantized and digitized form, is temporarily staged in buffer (step **105**), pending compression preparatory to storage in the flash memory **62** (step **106**). Following compression, the compressed ECG digitized sample is again buffered (step **107**), then written to the flash memory **62** (step **108**) using the communications bus. Processing continues (step **109**), so long as the monitoring recorder **14** remains connected to the electrode patch **15** (and storage space remains available in the flash memory **62**), after which the processing loop is exited and execution terminates. Still other operations and steps are possible.

While the invention has been particularly shown and described as referenced to the embodiments thereof, those skilled in the art will understand that the foregoing and other changes in form and detail may be made therein without departing from the spirit and scope.

What is claimed is:

1. An electrocardiography monitor, comprising:

a battery;

a non-conductive receptacle configured to house the battery;

a housing comprising rounded edges along a top surface, wherein the housing engages the non-conductive receptacle and the non-conductive receptacle is configured to receive the housing, wherein the battery is positioned between the housing and a bottom surface of the non-conductive receptacle;

a patient feedback button located on the top surface of the housing;

an electrographic front end circuit to sense electrocardiographic signals;

a distal electrocardiography electrode coupled to a distal end of a flexible circuit and a proximal electrocardiography electrode coupled to a proximal end of the flexible circuit, wherein the flexible circuit is coupled to a flexible backing and the flexible backing is configured to adhere to skin of a patient's chest; and

a microcontroller secured by the housing, wherein the microcontroller is interfaced to the electrocardiographic front end circuit to sample the electrocardiographic signals.

2. The electrocardiography monitor according to claim **1**, comprising:

a seal coupling surrounding electrical contacts, wherein the electrical contacts protrude from the bottom surface of the housing to connect to the battery to power the microcontroller.

3. The electrocardiography monitor according to claim **1**, further comprising:

electrical contacts to establish an electrical connection with the distal electrocardiography electrode and the proximal electrocardiography electrode for sensing the electrocardiographic signals.

4. The electrocardiography monitor according to claim **1**, wherein the housing is shaped for placement over the battery.

5. The electrocardiography monitor according to claim **1**, further comprising:

circuitry for an actigraphy sensor.

6. The electrocardiography monitor according to claim **5**, wherein the actigraphy sensor generates interrupt signals to the microcontroller based on a position of the housing.

7. The electrocardiography monitor according to claim **1**, wherein the housing comprises polycarbonate, ABS, or an alloy of polycarbonate and ABS.

8. The electrocardiography monitor according to claim 1, further comprising:

flash memory configured to store the electrocardiographic signals.

9. The electrocardiography monitor according to claim 1, further comprising:

an expansion port via which an external device interfaces to the microcontroller.

10. The electrocardiography monitor according to claim 9, wherein the external device comprises a physiological sensor.

11. An electrocardiography monitor assembly, comprising:

a battery compartment formed on a bottom surface of a non-conductive receptacle, wherein a battery is located in the battery compartment;

a housing comprising rounded edges along a top surface, wherein the non-conductive receptacle is configured to receive the housing and wherein the battery compartment is positioned between the housing and the bottom surface of the non-conductive receptacle;

an electrographic front end circuit to sense electrocardiographic signals;

a distal electrocardiography electrode coupled to a distal end of a flexible circuit and a proximal electrocardiography electrode coupled to a proximal end of the flexible circuit, wherein the flexible circuit is coupled to a flexible backing and the flexible backing is configured to adhere to skin of a patient's chest;

a microcontroller secured by the housing, wherein the microcontroller is interfaced to the electrocardiographic front end circuit to sample the electrocardiographic signals memory; and

a backing configured to receive the housing.

12. The electrocardiography monitor assembly according to claim 11, comprising:

a seal coupling surrounding electrical contacts.

13. The electrocardiography monitor assembly according to claim 11, further comprising:

electrical contacts to establish an electrical connection with the distal electrocardiography electrode and the proximal electrocardiography electrode for sensing the electrocardiographic signals.

14. The electrocardiography monitor assembly according to claim 11, wherein the housing is shaped to fit over the battery.

15. The electrocardiography monitor assembly according to claim 11, further comprising:

circuitry for an actigraphy sensor comprised within the housing.

16. The electrocardiography monitor assembly according to claim 15, wherein the actigraphy sensor generates interrupt signals to the microcontroller based on a position of the housing.

17. The electrocardiography monitor assembly according to claim 11, wherein the housing comprises polycarbonate, ABS, or an alloy of polycarbonate and ABS.

18. The electrocardiography monitor assembly according to claim 11, further comprising:

flash memory configured to store the electrocardiographic signals.

19. The electrocardiography monitor assembly according to claim 11, further comprising:

an expansion port comprised in the circuitry via which an external device interfaces to the microcontroller.

20. The electrocardiography monitor assembly according to claim 19, wherein the external device comprises a physiological sensor.

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